UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE METFORMIN MARKETING AND SALES PRACTICES LITIGATION	)	**Civil Action No. 2:20-cv-2324**

MANUFACTURER DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED CONSOLIDATED ECONOMIC LOSS CLASS ACTION COMPLAINT

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INTRODUCTION

In its May 20, 2021 Order (Dkt. 124) ("Order"), this Court dismissed Plaintiffs' Consolidated Economic Loss Class Action Complaint (Dkt. 58) ("Complaint" or "Compl.") for lack of standing and granted Plaintiffs 30 days to file an amended pleading "to the extent Plaintiffs can cure the deficiencies identified in this order[.]" Order at 5. The Court detailed the specific standing deficiencies Plaintiffs needed to cure to withstand dismissal, providing a road map for Plaintiffs' amended pleading. Yet in their First Amended Consolidated Economic Loss Class Action Complaint (Dkt. 128) (the "Amended Complaint" or "Am. Compl."), Plaintiffs largely ignore the Court's clear direction and fail to cure the standing deficiencies the Court identified. Plaintiffs also makes no attempt to cure the numerous additional defects the Manufacturer Defendants identified in their opening motion to dismiss. Accordingly, the Court should dismiss the Amended Complaint without further leave to amend.

In the Amended Complaint, like in the original Complaint, Plaintiffs assert claims on behalf of individual Consumer Plaintiffs and a third-party payor ("TPP") Plaintiff, as well as putative consumer and TPP class members. Plaintiffs' claims arise out of Defendants' manufacture, sale, and distribution of metformin-containing drugs ("MCDs") that allegedly were adulterated, misbranded, or unapproved due to the presence of a potential carcinogen known as N-nitrosodimethylamine

("NDMA"). *See generally* Am. Compl. ¶¶ 1-11. Like the original Complaint, the Amended Complaint contains numerous jurisdictional and facial defects.

As a threshold matter, Plaintiffs perpetuate the same two standing deficiencies the Court identified in the original Complaint: (1) the Consumer Plaintiffs do not allege they purchased or ingested any MCDs containing NDMA; and (2) Plaintiffs fail to connect each Manufacturer Defendant's actions to at least one injured Plaintiff because they do not allege which Manufacturer Defendants' drugs they purchased. Plaintiffs make no effort to cure the first deficiency, merely repeating the same allegations this Court already found deficient. Plaintiffs likewise fail to cure the second deficiency because Plaintiffs lump groups of Manufacturer Defendants together rather than alleging which individual Manufacturer Defendants' MCDs each Plaintiff purchased and how (if at all) the alleged MCDs caused each Plaintiff to be injured. Plaintiffs also continue to lack standing to bring claims under the laws of jurisdictions in which no Plaintiff suffered an alleged injury-in-fact.

Plaintiffs additionally fail to cure any of the other pleading defects identified in the Manufacturer Defendants' opening motion to dismiss:

- **Improper "Shotgun" Pleading**: The Amended Complaint remains a prototypical "shotgun" pleading. It spans 585 paragraphs and nearly 125 pages and asserts 22 claims directed against foreign and domestic defendants across the purported supply chains lumped together in group allegations. The Court should dismiss this improper pleading because it asserts claims generally against all Defendants without giving notice to each Defendant of its alleged wrongdoing and incorporates numerous irrelevant allegations without connecting them to any claim.

- **Preemption and Primary Jurisdiction**: The Court should dismiss the state-law claims for breach of warranty, fraud, negligent misrepresentation, consumer protection, unjust enrichment, negligence, and negligence *per se* as preempted by federal law. The Court should further dismiss the remaining state-law claims and defer to the primary jurisdiction of the U.S. Food & Drug Administration ("FDA") until it completes its agency action relating to MCDs.

- **Subsumption**: The Court should dismiss the negligence, negligence *per se*, unjust enrichment, and breach of implied warranty claims of all New Jersey and TPP Plaintiffs because their claims are subsumed by the New Jersey Products Liability Act.

- **Claim-Specific Deficiencies**: The Court should dismiss each individual claim for failure to state a claim.

- **Lack of Personal Jurisdiction**: The Court should dismiss the Amended Complaint for lack of personal jurisdiction as to Defendants Teva Pharmaceutical Industries, Ltd. ("Teva Industries"); Emcure Pharmaceuticals Ltd. ("Emcure"); Aurobindo Pharma Ltd.; and Alkem Laboratories Ltd. ("Alkem") (collectively, the "Non-U.S. Defendants") because Plaintiffs have not properly served and have failed to establish general or specific jurisdiction against the Non-U.S. Defendants.

This Court's Order was not a polite suggestion for Plaintiffs to follow or ignore at their whim. It defines the limits of Plaintiffs' standing and the Court's subject matter jurisdiction. Plaintiffs' failure to cure their standing deficiencies after an opportunity to amend confirms this Court cannot hear their claims. Likewise, Plaintiffs' failure to address pleading and jurisdictional defects that were apparent on the face of the original Complaint and persist in the Amended Complaint is equally fatal to their claims. For each reason, the Court should dismiss the Amended Complaint in its entirety without further leave to amend.

PROCEDURAL BACKGROUND

Plaintiffs' initial Complaint[1] asserted claims on behalf of seven individual Consumer Plaintiffs and one putative TPP Plaintiff, MSP Recovery Claims, Series LLC ("MSPRC"). Compl. ¶¶ 12-37. Defendants moved to dismiss the Complaint on various grounds, including lack of standing, lack of jurisdiction, and failure to state a claim, on October 8, 2020.[2] (Dkt. 78, 80). Following briefing, the Court entered its May 20, 2021 Order granting Defendants' motions to dismiss for lack of standing. (Dkt. 124).

Plaintiffs filed their Amended Complaint on June 21, 2021. (Dkt. 128). The Amended Complaint is filed by the same Plaintiffs,[3] asserts the same causes of action, and names as Defendants the same entities alleged to have manufactured, sold, or distributed generic MCDs, lumped into five groups of Manufacturer Defendants and four Pharmacy Defendants: Teva Pharmaceutical Industries Ltd.,

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[1] The original Complaint superseded eight separate complaints filed in discrete actions, which were consolidated before this Court for discovery and pretrial purposes. (*See* Dkt. 13, 76.)

[2] Certain Defendants (Amneal Pharmaceuticals, Inc.; AvKare, Inc.; Emcure; Aurobindo Pharma Ltd.; Alkem; and Teva Industries) did not join the Manufacturer's Defendants' motion to dismiss (Dkt. 78) because they had not been served in connection with the Complaint and/or in any action at the time the motion was filed. Defendants Amneal Pharmaceuticals, Inc.; AvKare, Inc.; and Teva Industries, subsequently filed joinders to the motion.

[3] Since the filing of the Complaint and Defendants' motions to dismiss, but prior to the Court's Order, another case, *Hendrix v. AvKare, Inc. et al*., Case No. 2:20-cv-00676 (E.D. Cal.), was consolidated with this litigation. (Dkt. 82). Plaintiff Hendrix does not join the Amended Complaint and asserts no allegations against Defendants.

Teva Pharmaceuticals USA, Inc., Actavis Pharma, Inc., and Actavis, LLC ("Teva/Actavis Entities"); Emcure Pharmaceuticals Ltd., Heritage Pharmaceuticals Inc. d/b/a Avet Pharmaceuticals, Inc.,[4] Granules USA, Inc., and Granules Pharmaceuticals, Inc.; Amneal Pharmaceuticals, Inc.,[5] Amneal Pharmaceuticals LLC, and AvKARE, Inc. ("Amneal Entities"); Aurobindo Pharma Ltd., Aurobindo Pharma USA, Inc., and Aurolife Pharma, LLC ("Aurobindo Pharma, Ltd. Entities"); Alkem Laboratories Ltd., and Ascend Laboratories, LLC ("Alkem/Ascend Entities"); Walgreens Boots Alliance, Inc.; CVS Health Corporation; Walmart Stores, Inc.; Rite-Aid Corporation; and various "John Doe" pharmacies and wholesalers. Am. Compl. ¶¶ 29-75.

In the Amended Complaint, Plaintiffs make essentially four sets of substantive revisions: (1) they allege that each Consumer Plaintiff purchased MCDs from one or more of the lumped groups of Manufacturer Defendants, Am. Compl. ¶¶ 12-18;

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[4] Heritage Pharmaceuticals Inc. was incorrectly identified as a Defendant in this litigation.

[5] Any claims against Amneal Pharmaceuticals, Inc. should be also dismissed for the independent reason that generally, "a parent corporation . . . is not liable for the acts of its subsidiaries." *United States v. Bestfoods*, 524 U.S. 51, 61 (1998). Amneal Pharmaceuticals Inc. is a holding company and the parent company of Amneal Pharmaceuticals LLC. (*See* Amneal Pharmaceuticals, Inc., Annual Report (Form 10-K) (March 2, 2020) at F-11 (noting that Amneal Inc. is a "holding company whose principal assets are Amneal [Pharmaceuticals LLC] Common Units").) As a holding company, Amneal Pharmaceuticals Inc. does not manufacture, distribute, or sell any metformin product. Thus, Amneal Pharmaceuticals, Inc. must be dismissed because "mere ownership of a subsidiary does not justify the imposition of liability on the parent." *Pearson v. Component Tech. Corp.*, 247 F.3d 471, 484 (3d Cir. 2001).

(2) they add a Pharmacy Defendant for each Consumer Plaintiff, though they do not allege that each Consumer Plaintiff purchased his or her MCDs at the referenced pharmacy, but only that each MCD "was purchased" by a Pharmacy Defendant from one of the lumped groups of Manufacturer Defendants, *id*.; (3) they add allegations describing how a purchased MCD can be identified and traced using its National Drug Code ("NDC"), *id*. ¶¶ 88-111; and (4) they delete a number of allegations regarding current Good Manufacturing Practices ("cGMPs"), *compare* Compl. ¶¶ 113, 119-21, 146-49 *with* Am. Compl. ¶¶ 139-73. Other than those limited revisions, the Amended Complaint is substantively identical to the original Complaint dismissed by the Court.

FACTUAL BACKGROUND

"Metformin…is an oral antihyperglycemic drug used as a first-line therapy in the treatment and management of type 2 diabetes" that "often is referred to as the 'gold standard' of diabetes management because it is well-tolerated and cost effective." *Id.* at ¶ 2. Metformin is available in an immediate-release ("IR") formulation typically administered several times daily with meals and an extended-release ("ER") formulation administered once daily. *See* FDA Alerts Patients and Health Care Professionals to Nitrosamine Impurity Findings in Certain Metformin Extended-Release Products (May 28, 2020) (available at https://www.fda.gov/news-

events/press-announcements/fda-alerts-patients-and-health-care-professionals-nitrosamine-impurity-findings-certain-metformin) ("5/28/20 FDA Alert").[6]

Plaintiffs allege the Manufacturer Defendants manufactured, sold, or distributed generic metformin. *See* Am. Compl. ¶¶ 28-75. Plaintiffs do not disclose what formulation(s) of metformin were manufactured, sold and/or distributed by each Defendant or lumped Defendant group.

On March 2, 2020, an online pharmacy named Valisure filed a Citizen Petition with FDA stating its testing found the presence of NDMA in certain lots of MCDs. Am. Compl. ¶¶ 260-262. On May 28, 2020, FDA announced its testing on the same lots showed elevated levels of NDMA in certain ER metformin products but "has not shown NDMA in immediate release (IR) metformin products (the most commonly prescribed type of metformin)." 5/28/20 FDA Alert. FDA subsequently reported it found NDMA above recommended acceptable intake levels only in "certain lots of metformin extended-release formulation." FDA, *Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry,* p. 3 (September 2020; revised February 2021) (available at https://www.fda.gov/media/141720/download).

[6] The Court may take judicial notice of FDA's public records. *Otsuka Pharma Co. v. Torrent Pharm. Ltd.*, 118 F. Supp. 3d 646, 655 n.7 (D.N.J. 2015).

Voluntary recalls of a number of ER metformin products took place thereafter. Am. Comp. ¶¶ 273-274. No IR metformin products have been recalled by FDA. *See* FDA, Search List of Recalled Metformin Products (current as of 6/16/21) (https://www.fda.gov/drugs/drug-safety-and-availability/search-list-recalled-metformin-products). On July 2, 2020, FDA published a manuscript entitled "A Cautionary Tale: Qualitative LC-HRMS Analytical Procedures for the Analysis of N-Nitrosodimethylamine in Metformin" in *The APPS Journal*, finding the method used by Valisure to quantify purported NDMA levels in the metformin products tested by Valisure and FDA was "inappropriate ... due to overestimation of NDMA caused by the presence of a substance that interfered with the testing results." FDA, Update – The APPS Journal Publishes FDA Paper on Metformin Testing (July 2, 2020) (available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin).

Plaintiffs filed their actions shortly after the submission of the Valisure Citizen Petition. The eight Plaintiffs named in the Amended Complaint hail from four states. Plaintiffs Joseph Brzozowski and Jacqueline Harris are residents of New Jersey. Am. Compl. ¶¶ 12, 14. Plaintiffs Michael Hann, Mohammad Rahman and Elaine Wohlmuth are residents of California. *Id*. ¶¶ 13, 16, and 18. Plaintiff Stelios Mantalis is a resident of New York. *Id*. ¶ 15. Plaintiff Kristin Wineinger is a resident of Indiana. *Id*. ¶ 17. MSPRC is a Delaware series limited liability company with a

principal place of business in Florida. *Id*. ¶¶ 19-27. MSPRC asserts claims as the putative assignee of TPPs that allegedly reimbursed non-party consumers' MCD purchases in six states (Connecticut, Florida, Maryland, New York, North Carolina, and Ohio). *Id*. ¶ 27.

Plaintiffs allege they purchased and TPPs reimbursed for MCDs obtained by Plaintiffs from various pharmacies. *Id.* ¶ 51. Plaintiffs' claims all rest on the theory that "Defendants … introduced adulterated and/or misbranded MCDs containing dangerous amounts of nitrosamines into the U.S. market." *Id*. ¶ 271. Plaintiffs allege the "presence of nitrosamines" due to supposed "gross deviations" from Current Good Manufacturing Practices ("cGMPs") has rendered Defendants' MCDs "non-bioequivalent" to their Reference Listed Drug ("RLDs"), making them "non-therapeutically equivalent to their RLDs" and breaching Defendants' "express warranties of sameness[.]" *Id*. ¶ 285.

Plaintiffs allege they sustained "economic damages" as a result of paying for or reimbursing Defendants' MCDs. *Id*. ¶ 11. Plaintiffs allege Defendants allowed and failed to discover NDMA in metformin; introduced NDMA-containing MCDs into the U.S. market; represented to consumers through "marketing or informational materials" that their MCDs complied with cGMPs and did not contain (or were not likely to contain) any ingredients besides those identified on the products' FDA-approved labels; and failed to ensure the accuracy of their MCDs' labels, advertising,

or marketing statements. *Id.* ¶¶ 256–271, 284, 285. Plaintiffs allege they "would not have paid for … Defendants' MCDs" had the presence of nitrosamines "been made known earlier[.]" *Id.* ¶¶ 12-18; *see also id.* ¶¶ 449, 462.

Plaintiffs seek to represent putative classes and subclasses of consumers and TPPs in the United States or, alternatively, in each individual state, who "paid any amount of money out of pocket for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by any Defendant." *Id.* ¶¶ 344-46.

Plaintiffs' theory of economic injury rests on assertions that "[a]dulterated misbranded, and/or unapproved MCDs … are essentially worthless" and "have no market value," that "[n]o reasonable consumer would have paid what they did" but for Defendants' alleged conduct, and that Plaintiffs and other putative class members "have been injured and suffered damages in the amount of the purchase price for their medications, the purchase price of any replacement medications, and any consequential damages resulting from the purchases[.]" *Id.* ¶¶ 290, 424, 437, 367; *see also id.* ¶¶ 376, 387, 396, 402, 410, 424, 437, 447, 460, 481, 487. Plaintiffs assert claims for breach of express and implied warranties; violation of the Magnuson-Moss Warranty Act; common-law fraud; negligent misrepresentation; violation of state consumer protection, legal remedies, and unfair competition statutes; unjust enrichment; negligence; and negligence per se, and allege economic

harm only or injury of an unspecified nature. *See id.* ¶¶ 367, 376, 387, 396, 404, 412, 425, 438, 446, 451, 459, 464, 470, 476, 481, 482, 487, 488, 498, 508, 516, 523, 524, 540, 559, 560, 572, 573, 583, 584, 585. Plaintiffs' prayer for relief omits any damages for physical injury and seeks economic damages, fees, statutory penalties, interest, restitution, and punitive damages. *Id.* at PRAYER FOR RELIEF.

Plaintiffs do not identify which specific Defendants' MCDs and lots were used to fill each Plaintiff's prescriptions, whether those MCDs and lots contained NDMA, when and where the purchases occurred, or what amounts were paid. Plaintiffs plead no specific representation made by any Defendant to any particular Plaintiff or the details thereof, no facts suggesting that Plaintiffs knew or chose which Defendants' MCDs were dispensed to them by their pharmacies, and no facts indicating how any representation or omission affected their purchase decisions. Plaintiffs do not say whether they obtained MCDs for personal consumption or for a family or household member. Plaintiffs do not allege whether anyone consumed the MCDs allegedly purchased by or dispensed to them.

Plaintiffs allege no physical or emotional injury from Defendants' MCDs, no increased risk of injury, and no screening for injury prescribed by a qualified physician. Plaintiffs do not allege any of their MCDs failed to deliver the same therapeutic benefit in treating and managing type 2 diabetes as any other batch or

any other manufacturers' MCDs. Plaintiffs do not allege that they incurred medical monitoring costs.

ARGUMENT

I. LEGAL STANDARD

A motion to dismiss for lack of standing is brought under Rule 12(b)(1) for lack of subject matter jurisdiction. *See In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 243 (3d Cir. 2012); *Bellentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007). "When subject matter jurisdiction is challenged under Rule 12(b)(1), the plaintiff must bear the burden of persuasion." *Kehr Packages, Inc. v. Fidelcor, Inc.*, 926 F.2d 1406, 1409 (3d Cir. 1991). A facial challenge to standing is evaluated under the same legal standard as a Rule 12(b)(6) motion. *Id*. "Thus, to survive a motion to dismiss for lack of standing, a plaintiff 'must allege facts that affirmatively and plausibly suggest that it has standing to sue.' Speculative or conjectural assertions are not sufficient." *Finkelman v. Nat'l Football League*, 810 F.3d 187, 194 (3d Cir. 2016) (citation omitted).

To survive a motion to dismiss under Rule 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (internal marks omitted). Plaintiffs must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action." *Bell Atlantic Corp. v. Twombly*, 550

U.S. 544, 555 (2007) (citations omitted). This requirement "asks for more than a sheer possibility that a defendant has acted unlawfully." *Iqbal*, 556 U.S. at 678.

Counts VII, VIII, XIX, and XX of the Amended Complaint are further subject to Rule 9(b)'s heightened pleading requirements because they sound in fraud. *See Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1102-05 (9th Cir. 2003). To satisfy Rule 9(b), "the plaintiff must plead or allege the date, time, and place of the alleged fraud or otherwise inject precision or some measure of substantiation into a fraud allegation." *Frederico v. Home Depot*, 507 F.3d 188, 200 (3d Cir. 2007). Plaintiffs must allege "all of the essential background facts that would accompany the first paragraph of any newspaper story—that is, the who, what, when, where, and how, of the events at issue." *In re Rockefeller Ctr. Props., Inc. Sec. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citation and quotation omitted).

II. GROUNDS FOR DISMISSAL

A. Plaintiffs' Claims Should be Dismissed for Failure to Cure Their Lack of Article III Standing

The Court dismissed Plaintiffs' Complaint under Rule 12(b)(1) because it failed to satisfy Plaintiffs' threshold burden of pleading Article III standing. Order at 2-5. To meet their burden, Plaintiffs must allege: "(1) an injury-in-fact that is actual or imminent and concrete and particularized, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's challenged conduct, and (3) is likely to be redressed by a favorable judicial decision." *Koronthaly v. L'Oreal USA, Inc.*, 374

F. App'x 257, 259 (3d Cir. 2010); *see also Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016); *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992).

In its Order, the Court identified two standing defects in Plaintiffs' Complaint. First, the Consumer Plaintiffs "have failed to demonstrate that they suffered an injury as they have not alleged that they purchased or ingested any MCDs containing NDMA," because "although each Consumer Plaintiff alleges that they bought a product that was not the same as the [RLD] and that was 'illegally and willfully introduced into the market by Defendants,' … they do not allege that they purchased NDMA-contaminated MCDs from Defendants." Order at 3. Second, Plaintiffs "have not shown causation because they have failed to connect each Defendant['s] actions to at least one injured Plaintiff," insofar as "no Consumer Plaintiff alleges (1) which Manufacturer Defendant's drug they purchased, or (2) at which Pharmacy Defendant they purchased their drugs, so the Court, therefore, cannot link each Defendant to any injury suffered by any Consumer Plaintiff." *Id*. at 4. The Amended Complaint does not cure either problem. It disregards the first deficiency altogether, and employs lump allegations failing to cure the second deficiency.

1. The Amended Complaint Does Not Address Plaintiffs' Failure to Allege an Injury-in-Fact

The Court's Order clearly spells out how the Consumer Plaintiffs could remedy their failure to plead an injury-in-fact: They must allege plausible facts demonstrating that they "purchased or ingested any MCDs containing NDMA[.]"

Order at 3. The Amended Complaint contains no such allegations as to any Consumer Plaintiff. Instead, it repeats the same allegations this Court already found insufficient—that Plaintiffs "bought a product that was not the same as the RLD," and that was "illegally and willfully introduced into the market by Defendants[.]" Am. Compl. ¶¶ 11-18. The Court already flatly rejected the sufficiency of those allegations, finding they lack the necessary factual allegation that Plaintiffs purchased NDMA-contaminated MCDs from Defendants. Order at 3. Indeed, even as the Amended Complaint adds multiple allegations regarding the putative source and warranties of each Consumer Plaintiff's MCDs, it conspicuously omits ***any*** allegation that ***any*** Consumer Plaintiff ever actually purchased an MCD containing NDMA. *See* Am. Compl. ¶¶ 11-18.

The Consumer Plaintiffs' failure to allege they individually purchased MCDs containing NDMA precludes Article III standing under the injury-in-fact requirement. To demonstrate an injury-in-fact, a plaintiff must "allege an injury ***to himself*** that is 'distinct and palpable,' as opposed to merely '[a]bstract,' and the alleged harm must be actual or imminent, not 'conjectural' or 'hypothetical.'" *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (emphasis added, internal quotations omitted). *See also Spokeo*, 136 S. Ct. at 1548. Because no Consumer Plaintiff alleges he or she actually purchased or ingested any contaminated MCDs, the Consumer Plaintiffs cannot show, as they must, "that they themselves suffered

an injury[.]" Order at 3 (citing *Spokeo*, 136 S. Ct. at 1547 n.6).

The new allegations in the Amended Complaint reinforce the point that, if Plaintiffs had individually purchased MCDs containing NDMA, they are capable of ascertaining that fact and including it in their amended pleading. Plaintiffs allege each MCD contains an FDA-issued unique NDC that can be tracked from the manufacturer all the way through retail dispensing, displayed on the retail prescription label and often accompanied by the lot number used to report issues arising around a particular drug. Am. Compl. ¶¶ 86-89. Moreover, Plaintiffs incorporate FDA's recall announcements and accompanying public statements, including its statement that NDMA had only been found in "certain MCDs" and publication of a list of affected MCDs. *Id*. ¶¶ 281-82.

Alleging whether an individual Consumer Plaintiff purchased MCDs containing NDMA, therefore, is a simple matter of looking up the NDC on each Consumer Plaintiff's prescription and comparing it against FDA's list of NDMA-containing MCDs. Many MCDs ***do not*** fall within that group. For example, as discussed, FDA's statements have made clear that its testing has not shown NDMA in IR products (the most commonly prescribed type of metformin), and no IR products have been recalled.[7]

[7] That fact is important because, for example, Defendants Aurobindo Pharma USA, Inc., and Ascend Laboratories, Inc., did not sell ER products subject to FDA recall, and FDA's testing of the batch of Aurobindo and Ascend IR MCDs previously tested

Plaintiffs' failure to allege that the Consumer Plaintiffs purchased MCDs containing NDMA is thus not explainable by lack of access to the relevant information. The Consumer Plaintiffs had the ability to cure their failure to allege an injury-in-fact if their prescription records had supported such an allegation. That they did not indicates either that they ignored the Court's Order or that they simply lack the requisite factual support to allege an injury-in-fact. In either event, the Consumer Plaintiffs lack standing.

Plaintiffs further lack standing because they have not alleged an injury-in-fact, either physical or economic, from their purchases. The Consumer Plaintiffs allege no physical injury, and "the fear of future injury is legally insufficient to confer standing." *James v. Johnson & Johnson Consumer Co., Inc.*, No. 2:10-cv-03049, 2011 WL 198026, at *2 (D.N.J. Jan. 20, 2011); *see also TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2211 (2021). Similarly, although the TPP Plaintiff, MSPRC, alleges its assignors "made payments for the Manufacturer Defendants' MCDs contaminated with NDMA," and purports to provide "sample" payments made by its assignors (*see* Am. Compl. ¶ 27), it does not allege any of the patients listed as "samples" actually were physically injured.

Additionally, though the Consumer Plaintiffs insist their MCDs were

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by Valisure did not detect NDMA. *See* FDA, Laboratory Analysis of Metformin Products (available at https://www.fda.gov/drugs/drug-safety-and-availability/laboratory-tests-metformin).

"worthless" to the extent they contained NDMA, they do not allege any diminution in efficacy or other objective factual basis to conclude they were denied the benefit of their bargain. *See Koronthaly*, 374 F. App'x at 259 (holding that, "[a]bsent any allegation that [plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect," she "could not have been denied the benefit of any bargain"). A plaintiff "who has entirely consumed a product that has functioned for her as expected" does not "suffer an economic injury solely because she now sincerely wishes that she had not purchased that product[.]" *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Prac. & Liab. Litig.*, 903 F.3d 278, 280-81 (3d Cir. 2018). To establish an economic injury-in-fact, a plaintiff must "allege facts that would permit a factfinder ***to value the purported injury*** at something more than zero dollars without resorting to mere conjecture." *Id.* at 285 (emphasis added). That allegation is missing here.

Plaintiffs' inability to plead a cognizable injury-in-fact after notice, an opportunity to amend, and unambiguous instructions regarding what facts to include to cure the deficiency "to the extent Plaintiffs can" (Order at 5) indicates Plaintiffs' Amended Complaint "cannot be saved" and should be dismissed without further leave to amend. *See Wolferd v. Phelan*, No. 09-1302, 2013 WL 6061562, at *7 (E.D. Pa. Nov. 14, 2013); *see also Lawson v. City of Phila.*, No. 18-1912, 2020 WL 1028042, at *5 (E.D. Pa. Mar. 2, 2020) (citing *Travelers Indem. Co. v. Cephalon,*

Inc., 620 F. App'x 82, 87 (3d Cir. 2015) (denying leave to amend as futile where plaintiff "has already been given an opportunity to amend," court "was very specific in pointing out the deficiencies," and plaintiff "failed to cure same").

2. The Amended Complaint Does Not Cure Plaintiffs' Failure to Allege an Injury Traceable to Each Defendant

The Amended Complaint also fails to sufficiently address the second deficiency the Court identified—Plaintiffs' failure "to connect each Defendant['s] actions to at least one injured Plaintiff[.]" Order at 4 (citing *Cent. States Se. & Sw. Area Health & Welfare Fund v. Merck-Medco Managed Care, LLC*, 504 F.3d 229, 241 (2d Cir. 2015)). Plaintiffs' attempted solution to that failure is to add allegations that each Consumer Plaintiff purchased "MCDs manufactured, distributed, or sold" by lumped-together groups of Manufacturer Defendants. Am. Compl. ¶¶ 12-18. Plaintiff Brzozowski, for example, asserts that he purchased unspecified "Teva Product" sold by "the Teva Defendants," a group definition comprising four separate and distinct entities. *Id*. ¶¶ 12, 29-32. The Amended Complaint makes similar allegations purporting to link each Consumer Plaintiff to purchases of unidentified MCD products from lumped groups of Manufacturer Defendants. *Id*. ¶¶ 13-18.

Plaintiffs' group pleading does not cure the deficiency identified by the Court. The Order was again unambiguous; to cure the second standing deficiency, Plaintiffs were obliged "to connect ***each Defendant['s]*** actions" to an injured Plaintiff. Order at 4 (emphasis added). Putting aside that every Consumer Plaintiff failed to allege

any injury at all, *see* § II.A.1, *supra*, Plaintiffs' lumping of Manufacturer Defendants together fails to trace ***each Defendant's*** actions to at least one Consumer Plaintiff's asserted injury. "[I]n order to establish standing in the class action context, for ***each named defendant***, at least one named plaintiff must be able to allege an injury ***traceable to that defendant***." *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, No. MDL 2875 (RBK/JS), 2021 WL 100204, at *13 (D.N.J. Jan. 12, 2021) (emphasis added). The Amended Complaint falls well short.

Plaintiffs' task was not difficult. Plaintiffs readily could have used their NDCs to identify the ***specific*** Manufacturer Defendant entity responsible for manufacturing, distributing, or selling each Plaintiff's MCDs. Their decision not to do so, in the face of their admitted ability to comply, evidences a tactical choice to muddy their pleadings in the hopes of retaining Manufacturer Defendants in the case that must otherwise be dismissed for lack of traceability.[8] That is why, as discussed below, the Court should not countenance Plaintiffs' "shotgun" pleading tactics.

[8] MSPRC's allegations contain a further uncured defect as to traceability specific to the TPPs. MSPRC's assignors are not consumers of the MCDs they reimburse, and do not allege facts tracing the Manufacturer Defendants' conduct to a "distinct and palpable" loss to the TPPs. *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990) (internal quotations omitted). MSPRC alleges only that its TPP assignors reimbursed their members' MCD purchases. *See* Am. Compl. ¶ 27. It does not allege its assignors had to reimburse new or additional purchases or pay more as a result of alleged impurities or that the MCDs purchased by the "sample" patients contained NDMA. The source of the TPPs' economic loss, separate from the consumers' putative loss, is absent, and MSPRC cannot rely on the consumers' putative injuries for standing. *See* Order at 3 ("[A] class representative must show that they themselves suffered

3. Plaintiffs Lack Standing to Bring Claims Across All States

Lastly, putative class representatives lack standing "to assert claims under the laws of states where they do not reside and were not injured[.]" *In re Valsartan*, 2021 WL 100204, at *14. *See also Ponzio v. Mercedes-Benz USA, LLC*, 447 F. Supp. 3d 194, 222 (D.N.J. 2020); *In re Insulin Pricing Litig.*, No. 3:17-CV-0699-BRM-LHG, 2019 WL 643709, at *17 (D.N.J. Feb. 15, 2019); *Cooper v. Medimetriks Pharms., Inc.*, No. 18-11987, 2019 WL 1370414, at *4 (D.N.J. Mar. 25, 2019); *In re Magnesium Oxide Antitrust Litig.,* No. 10-cv-5943, 2011 WL 5008090, at *25-26 (D.N.J. Oct. 20, 2011). The Consumer Plaintiffs allege residence in four states – California, Indiana, New Jersey, and New York – and do not allege any injuries outside those states. Am. Compl. ¶¶ 12-18. MSPRC alleges residence in Delaware and Florida, and asserts claims for reimbursements made in six states – Connecticut, Florida, Maryland, New York, North Carolina, and Ohio. *Id*. ¶¶ 19, 27. Though

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an injury and cannot merely rely upon the standing of individuals in the proposed class[.]" (citing *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 n.6 (2016)). Moreover, allegations of adulteration, misbranding, or noncompliance with cGMPs cannot as a matter of law provide a basis for economic recovery of reimbursed Medicare payments, because "all that is required [for Medicare payment] is that a drug be approved by the FDA." *United States ex rel. Campie v. Gilead Sci., Inc.*, No. C-11-0941 EMC, 2015 WL 106255, at *7-11 (N.D. Cal. Jan. 7, 2015) (rejecting False Claims Act claim for recovery of Medicare payments for allegedly adulterated drugs). MSPRC does not dispute that its assignors reimbursed purchases of FDA-approved MCDs, and thus has not alleged that the Manufacturer Defendants' alleged conduct is traceable to any distinct and palpable economic loss incurred by MSPRC or its assignors.

MSPRC alleges its assignors made payments "for Defendants' drugs" in other states and territories, it does not allege payments for "contaminated Metformin drugs" in any states other than the six "sample" states. *Id*. ¶ 27. Yet Plaintiffs assert claims under the laws of all 50 states, Washington, D.C., and Puerto Rico. *Id*. ¶¶ 365, 375, 381, 392. The Court should dismiss all claims asserted under the laws of all states and territories lacking allegations establishing standing.

B. Plaintiffs' Amended Complaint Remains an Improper Shotgun Pleading

Plaintiffs' rambling Amended Complaint also should be dismissed in its entirety as an impermissible "shotgun" pleading that obfuscates more than illuminates what wrongdoing is asserted by whom against whom. The Amended Complaint slogs through 585 paragraphs across more than 120 pages, with 356 prefatory paragraphs followed by 22 counts. Each count begins with the same generic incorporation clause: "Plaintiffs re-allege and incorporate the preceding paragraphs as if fully set forth herein," meaning each count also incorporates every preceding count. And despite naming a litany of Defendants at all levels of the purported chains of distribution, including dozens of "John Doe" Defendants, Plaintiffs do not allege who did what to whom. Instead, every one of Plaintiffs' 22 counts is directed to "all Defendants," or "all Defendants except Pharmacy Defendants," and each count is rife with vague and conclusory allegations directed to "Defendants" or "each Defendant" without even once articulating the requisite

factual basis for any individual Defendant's alleged misconduct.

That is a far cry from the "short and plain statement" of Plaintiffs' claims required by Rule 8(a)(2). The courts of the Third Circuit have followed the Eleventh Circuit in prohibiting such "shotgun pleading." *See Bartol v. Barrowclough*, 251 F. Supp. 3d 855, 859 (E.D. Pa. 2017) (quoting *Weiland v. Palm Beach Cnty. Sheriff's Office*, 792 F.3d 1313, 1320 (11th Cir. 2015)); *see also Hynson By and Through Hynson v. City of Chester Legal Dep't*, 864 F.2d 1026, 1031 n.13 (3d Cir. 1988) (criticizing the "all too common shotgun pleading approach"). A "shotgun pleading" strategy "flouts Rule 8, which does not countenance enigma[.]" *Gov't Employees Ins. Co. v. Pennsauken Spine & Rehab P.C.*, No. CV1711727RBKKMW, 2018 WL 3727369, at *3 (D.N.J. Aug. 6, 2018) (citing *Weiland*, 792 F.3d at 1323).

The Amended Complaint exemplifies three types of "shotgun" pleading: (1) it contains "multiple counts where each count adopts the allegations of all preceding counts"; (2) it is "replete with conclusory, vague, and immaterial facts not obviously connected to any particular cause of action"; and (3) it "assert[s] multiple claims against multiple defendants without specifying which of the defendants are responsible for which acts or omissions, or which of the defendants the claim is brought against." *Bartol*, 251 F. Supp. 3d at 859 (quoting *Weiland*, 792 F.3d at 1321-23). The "unifying characteristic" of these types of shotgun pleadings "is that they fail to one degree or another, and in one way or another, to give the defendants

adequate notice of the claims against them and the grounds upon which each claim rests." *Id.* (quoting *Weiland*, 792 F.3d at 1323). *See also Murphy v. Hotwire Commc'ns, LLC*, No. CV 19-5901, 2020 WL 2128472, at *6 (E.D. Pa. May 5, 2020).

Each of the Amended Complaint's 22 counts against "all Defendants" or "all Defendants except Pharmacy Defendants" adopts the allegations of all preceding paragraphs and preceding counts, and contains innumerable conclusory, vague, and immaterial facts directed against "Defendants" or "each Defendant." Though the 356 prefatory paragraphs contain allegations about some of the Defendants, Plaintiffs make no effort to inform the Court or the Defendants which allegations pertain to which claims by which Plaintiffs against which Defendants. The dozens of named and unnamed Defendants in the Amended Complaint are not fungible; they are distinct entities with separate corporate existence. *See* Am. Compl. ¶¶ 28-70. Plaintiffs' allegations fall woefully short of apprising each Defendant of the purported claim or claims against it.

As was true of the "shotgun pleading" this Court found wanting in *Government Employees Insurance*, Plaintiffs' Amended Complaint is "sprawling and inscrutable." 2018 WL 3727369, at *3. Its incorporation of all previous allegations and all previous counts into each new count leads to "computationally impossible statements" and a "logarithmic expansion of paragraphs as each count incorporates previous incorporations that themselves incorporated incorporations."

Id. "Each successive count thus snowballs into a blizzard of theories, facts, allegations, and claims which must be shoveled away before the blob beneath the snowbank reveals itself as a car, house, or plausible … dispute." *Id*. "By incorporating all preceding allegations into each count, Plaintiff[s] engage in shotgun pleadings that obfuscate [their] claims and defy the mandate of Rule 8, denying Defendants of the fullest extent of notice to which they are entitled." *Lapella v. City of Atl. City*, No. CIV. 10-2454 JBS/JS, 2012 WL 2952411, at *5 n.3 (D.N.J. July 18, 2012); *see also In re: Zantac (Ranitidine) Prod. Liab. Litig.*, MDL No. 2924, 2020 WL 7866674, at *11 (S.D. Fla. Dec. 31, 2020).[9]

This Court should not countenance Plaintiffs' attempt at do-it-yourself pleading, in which Plaintiffs supply an endless litany of oblique, vague insinuations lacking context or specificity, and the Court and Defendants are left to sift through the clutter in search of the absent components of a plausible claim. Consider Plaintiffs' attempts to cast Defendants as bad actors using scurrilous allegations such as purported deficiencies noted during past FDA inspections or actions. *See* Am.

[9] This Court repeatedly has dismissed less egregious examples of shotgun pleadings than the present Amended Complaint. *See, e.g., K.J. & T.J. ex rel. K.J., Jr. v. Greater Egg Harbor Reg'l High Sch. Dist. Bd. of Educ*., Civ. No. 14-145 (RBK/JS), 2015 WL 5039460, at *6 (D.N.J. Aug. 26, 2015) (100-page complaint against 17 defendants); *Falat v. Cnty. of Hunterdon*, Civ. No. 12-6804 (SRC), 2013 WL 1163751, at *3 (D.N.J. Mar. 19, 2013) (57-page complaint against 16 defendants); *see also Bartol*, 251 F. Supp. 3d at 859 (54-page complaint asserting 13 counts against 7 defendants).

Compl. ¶¶ 173-247. Or consider Plaintiffs' descriptions of purported content from company websites, which they characterize as "warranties." *Id.* ¶¶ 295-331. Plaintiffs do not say what those allegations have to do with Plaintiffs' individual MCD purchases or their claims against each Defendant. They leave that for the Court and Defendants to puzzle out. Except "[a] complaint is not a puzzle," and courts should be "loathe [sic] to allow plaintiffs to tax defendants, against whom they have levelled very serious charges, with the burden of solving puzzles in addition to the burden of formulating an answer to their complaint." *In re Glenfed, Inc. Securities Litig.*, 42 F.3d 1541, 1554 (9th Cir. 1994).

In sum, the Amended Complaint inevitably leads the parties and the Court into a pretrial quagmire. It should be dismissed.

C. Plaintiffs' State-Law Claims Are Preempted or Subject to the Primary Jurisdiction Doctrine

1. Federal Law Preempts Plaintiffs' State-Law Claims Seeking to Privately Enforce the Federal Food, Drug, and Cosmetic Act or FDA Regulations

Many of Plaintiffs' state-law claims are preempted as invalid attempts to privately enforce the Federal Food, Drug, and Cosmetic Act ("FDCA") and FDA regulations. Only the federal government has the authority to enforce the FDCA, and private litigants are forbidden to bring "proceedings for the enforcement, or to restrain violations, of" the statute. 21 U.S.C. § 337(a); *see also Farina v. Nokia Inc.*, 625 F.3d 97, 124 (3d Cir. 2010); *Brooks v. Mentor Worldwide LLC*, 985 F.3d 1272,

1280 (10th Cir. 2021). The Supreme Court has interpreted this exclusion to impliedly preempt state-law claims if "the existence" of the FDCA "is a critical element" of the claim. *Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 353 (2001).

The FDA has cautioned that private litigants not be allowed to "circumvent this straightforward prohibition" by "wrapping their FDCA enforcement claims inside some *other* cause of action." Brief for FDA as Amicus Curiae at 7, 10, *Amarin Pharma, Inc. v. ITC*, No. 2018-1247 (3d Cir. Mar. 27, 2018) ("FDA Amicus"). *See also Excela Pharma Sciences, LLC v. Sandoz Inc.*, 486 F. Supp. 3d 1001, 1012 (W.D.N.C. Sept. 15, 2020) (holding FDCA's "prohibition on private actions … would be thwarted if savvy plaintiffs can label as arising under a state law … a claim that in substance seeks to enforce the FDCA," and therefore "private litigants may not bring a state-law claim against a defendant when the state-law claim is in substance (even if not in form) a claim for violating the FDCA") (citations omitted).

Thus, the FDCA "precludes those private proceedings that rely on alleged violations of the FDCA as a necessary component of their cause of action[.]" FDA Amicus at 10-11 (quoting § 337(a)). If the state-law claim depends on concepts or standards that exist "solely" because of the FDCA, it does not flow from a pre-existing state-law duty and is preempted. *Buckman*, 531 U.S. at 352-53; *see Jankowski v. Zydus Pharms. USA, Inc*, No. 20-2458 (MAS) (TJB), 2021 WL 2190913 at *3 (D.N.J. May 28, 2021) (holding claims "couched in traditional state

tort law" preempted where "it is clear the existence of the FDA's Medication Guide regulation is the gravamen of these claims") (quoting *Frei v. Taro Pharm. U.S.A., Inc.,* 443 F. Supp. 3d 456, 458 (S.D.N.Y. 2020)); *see also Markland v. Insys Therapeutics, Inc.,* 758 F. App'x 777, 779-80 (11th Cir. 2018) (per curiam).[10]

2. Plaintiffs' State-Law Claims Are Disguised Attempts to Privately "Enforc[e]" or "Restrain Violations" of the FDCA

Plaintiffs attempt to do what Congress has prohibited by dressing up their private attempts to enforce federal law as state-law negligence *per se*, negligence, unjust enrichment, fraud, warranty, and consumer protection claims. But beneath the window-dressing, those claims are just attempts to enforce the FDCA. Preemption

[10] Judge Kugler in the *In re Valsartan* MDL limited implied preemption under *Buckman* to claims of fraud-on-the-FDA on the rationale that such a claim presents a "unique circumstance." *In re Valsartan, Losartan, and Irbesartan Prods. Liab. Litig.*, No. 2875 (RBK-JS), *slip op.* at 12, 2020 WL 7418006, at *9 (D.N.J. Dec. 18, 2020) (quoting *Tigert v. Ranbaxy Pharms., Inc.*, Civ. No. 12–00154, 2012 WL 6595806, at *3 (D.N.J. Dec. 18, 2012)). But as more recent precedent reaffirms, the express language of *Buckman* requires its application to all claims that exist "solely by virtue" of the FDCA's requirements. *See Jankowski*, 2021 WL 2190913 at *3. Indeed, holding otherwise would undercut the very rationale of the *Buckman* decision (not to mention Section 337(a)) by permitting plaintiffs to undertake private enforcement of the FDCA simply by assigning any nomenclature other than "fraud-on-the-FDA" to their private enforcement claims. The *In re Valsartan* ruling also mistakenly references an impossibility preemption decision, *Wyeth v. Levine*, 555 U.S. 555 (2009), as the "latest, single-most, on-point Supreme Court case[.]" *In re Valsartan, slip op.* at 10. But *Wyeth* addresses the distinct issues of impossibility preemption (whether it is possible to comply simultaneously with federal and state law) and obstacle preemption (whether state law presents an obstacle to the enforcement of federal law), not impermissible efforts to privately enforce the FDCA. *See Wyeth*, 555 U.S. at 563. In fact, the *Wyeth* majority specifically noted that *Buckman* involved a separate and distinct type of preemption. *Id.* at 565 n.3.

"applies to claims like breach of warranty [and] negligence per se" where the claim "relies on the FDCA or its implementing regulations as a critical element[.]" *Excela Pharma Sciences*, 2020 WL 5535026, at *5.

Crucially, and as even the Amended Complaint's headings confirm,[11] Plaintiffs' claims depend on proving a violation of the FDCA itself, or of a concept or standard that exists solely due to the FDCA. Plaintiffs' claims depend on establishing that Defendants violated the FDCA's requirements regarding the manufacture and sale of "adulterated drugs" that are, *inter alia*: non-compliant with cGMPs, 21 U.S.C. § 351(a)(1); different from their approved brand-name counterpart in violation of the FDCA's "duty of sameness," *id*. §§ 321(m), 351(b), 355(j)(2)(A); or mixed with a substance that reduces their quality, *id*. § 351(d). *See* Am. Compl. ¶¶ 110-328. Whether based on Defendants' alleged conduct or alleged statements and omissions, each claim depends on proving a violation of a concept or standard that exists solely by virtue of the FDCA and is therefore an impermissible and preempted attempt to privately enforce the FDCA.

Negligence *Per Se* (Counts XVII and XVIII). Negligence *per se* is the

[11] *See, e.g.,* Am. Compl. ¶¶110-18 ("Drugs Must Be Manufactured in Compliance with Good Manufacturing Practices"); *id*. ¶¶ 119-29 ("Adulterated or Misbranded Drugs Are Illegal to Sell"); *id*. ¶¶ 130-38 ("The Drugs Purchased by Plaintiffs Were Not Metformin, But Adulterated and Misbranded Drugs, Not of the Same Quality"); *id*. ¶¶ 155-231 ("Defendants Were Actively Violating cGMPs in Their Foreign Manufacturing Facilities"); *id*. ¶¶ 232-47 ("Defendants' Action Resulted in Adulterated and Misbranded MCDs Contaminated with NDMA").

clearest example of a private attempt to enforce the FDCA masquerading as a state-law claim. Plaintiffs rely entirely on allegations that Defendants failed to comply with requirements of the FDCA, including the sameness requirement and the cGMP provisions. *See, e.g.*, Am. Compl. ¶¶ 497, 499, 505, 507. The Third Circuit has squarely rejected such attempts to create a *de facto* private cause of action for the violation of a federal statute that precludes private claims. "This interpretation of per se liability would allow private plaintiffs to recover for violations of a federal statute that creates no private cause of action and, in fact, expressly restricts its enforcement to the federal government." *In re Orthopedic Bone Screw Products*, 193 F.3d 781, 791 (3d Cir. 1999); *Brooks,* 985 F.3d at 1280.[12] Plaintiffs' reference to "parallel state statutes," *id*. at ¶ 506, cannot salvage their claims, as Plaintiffs have not identified *any* statutory standard of care under any state statutes other than verbatim adoption of the standards supplied by the FDCA—which the federal government alone can enforce. *See Jankowski,* 2021 WL 2190913 at *6 (rejecting plaintiff's negligence per se claims premised on FDA regulations).

Negligence (Counts XV and XVI). The negligence claims likewise rely entirely on Defendants' purported failure to abide by their duties under the FDCA,

[12] *See also Dunbar v. Medtronic, Inc.*, No. CV-14-01529-RGK(AJWx), 2014 WL 3056026, at *6 (C.D. Cal. June 25, 2014); *Leonard v. Medtronic, Inc*., No. 1:10-CV-03787-JEC, 2011 WL 3652311, at *7 (N.D. Ga. Aug. 19, 2011); *In re Bard IVC Filters Prod. Liab. Litig*., MDL 15-02641-PHX-DGC, 2018 WL 4356638, at *2 (D. Ariz. Sept. 12, 2018).

including therapeutic equivalence and the prohibitions on adulteration and misbranding. Am. Compl. ¶¶ 477, 487. Those claims also are preempted. *Cf. Markland*, 758 F. App'x at 779-80 (applying preemption to negligence claim where "the substance of [the] complaint" disclosed a "critical premise" of the claim was that the defendant "violated federal law," a proposition "that can only be established by pointing to federal law").[13]

Breach of Express Warranty, Common Law Fraud, and Negligent Misrepresentation (Counts I-II, VII-VIII, and IX-X). Plaintiffs' claims for breach of express warranty, common law fraud, and negligent misrepresentation all rely wholly on allegations that Defendants falsely warranted or represented that their MCDs complied with the FDCA when they purportedly did not. Am. Compl. ¶¶ 265-

[13] To the extent Plaintiffs allege use of the FDA-approved design or manufacturing process itself was negligent, that claim is subject to conflict preemption because Defendants could not deviate from the FDA-approved design for metformin unless and until they received FDA approval. *See In re Zantac (Ranitidine) Prod. Liab. Litig.,* MDL No. 2924, 2020 WL 7864213 at *13 (S.D. Fla. Dec. 31, 2020) ("[Supreme Court precedent] dictate[s] that Plaintiffs' claims are pre-empted if they are based on alleged product defects that Defendants could not independently change while remaining in compliance with federal law, even if those defects rendered the products misbranded"); *In re Fosamax (Alendronate Sodium) Prod. Liab. Litig. (No. II)*, No. CIV. 08-008 GEB-LHG, 2011 WL 5903623, at *6 (D.N.J. Nov. 21, 2011); *see also Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 477 (2013). Indeed, in recent guidance addressing the presence of nitrosamine in MCDs, the FDA mandated: "Drug manufacturers *must* report changes implemented to prevent or reduce nitrosamine impurities in accordance with FDA regulations (21 CFR 314.60, 314.70, 314.96, and 314.97)." FDA, Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry at 16 (September 2020) (available at https://www.fda.gov/media/141720/download).

316, 345-50, 355-60, 400-02, 413-15, 426-29, 439-43. Those fraud-on-the-public claims fail as variants of the same fraud-on-the-FDA claims held preempted in *Buckman* because they likewise are entirely dependent on proving a violation of the FDCA's sameness or cGMP requirements. Put differently, if the MCDs *did* comply with the FDCA's sameness and cGMP requirements, or if those federal requirements did not exist, then there would be no grounds for relief. Plaintiffs' basic allegation is that deviations from the FDCA's requirements rendered the drugs "adulterated and/or misbranded compared to Defendants' representations and warranties." Am. Compl. ¶ 271; *see also, e.g.*, *id*. ¶¶ 401, 414, 426, 438.

Because the entire basis for Plaintiffs' warranty, fraud, and negligent misrepresentation claims is noncompliance with the FDCA, noncompliance is a "critical element" of these claims. *See Perez v. Nidek Co.*, 711 F.3d 1109, 1119 (9th Cir. 2013) (holding fraud by omission claim impliedly preempted because issue of FDCA compliance depended on questions that "rest within the enforcement authority of the FDA, not this Court." (quotation marks and citation omitted)). To hold otherwise invites private enforcement of the FDCA by simply alleging that Defendants represented that they complied with the FDCA but did not. Such representations cannot serve as the basis for a claim under state law. *See D'Addario v. Johnson & Johnson*, No. 3:10-cv-15627, 2021 WL 1214896 at *7 (D.N.J. Mar. 31, 2021) (holding breach of warranty and negligent misrepresentation claims

preempted because they relied on finding that "defendants misrepresented that defendant's device was safe—which directly contradicts the FDA's finding that the device is safe and effective") (internal quotation marks omitted); *Amarin Pharma, Inc. v. Int'l Trade Comm'n*, 923 F.3d 959, 969 (Fed. Cir. 2019) (holding false-advertising claim precluded because the claim "require[d] proving a violation of the FDCA itself"). *See also* FDA Amicus, at 17-20 (collecting cases).

Unjust Enrichment (Counts XIII and XIV). Plaintiffs' unjust enrichment claims rely on allegations that "Defendants profited immensely" from "illegal" sales of "adulterated and misbranded" MCDs. Am. Compl. ¶¶ 465, 471. Plaintiffs' only specific allegations related to unjust enrichment rely on allegations that the sale of MCDs was "illegal" in the United States because those drugs were "adulterated" and "misbranded." *Id*. ¶¶ 465, 471. The Amended Complaint's unjust enrichment claims thus depend on proving a violation of the FDCA—indeed, that sale of the MCDs was "illegal" under the FDCA—and therefore these claims are preempted.

State Consumer Protection Laws (Counts XI-XII, IX-XXII). Plaintiffs' claims under the consumer protection laws of California, New York, and various other states also depend on establishing a violation of the FDCA and are preempted.

Plaintiffs' claim under the California Unfair Competition Law claim is preempted because it expressly depends on proof that Defendants' actions "violate the FDCA and implementing regulations," including "failure to comply with

cGMPs" and the "prohibition on introduction of adulterated and misbranded medications into interstate commerce." Am. Compl. ¶ 533 (statutory citations omitted).

The other state consumer protection claims are wholly conclusory in their alleged violations. *See* Am. Compl. ¶¶ 452, 455, 458, 461, 552, 568. Because they necessarily rely on Plaintiffs' prefatory allegations of fraud dependent upon alleged FDCA and regulatory violation, *see id*. at ¶¶ 265-316, they too are preempted.

3. The Court Should Dismiss or Abstain from Deciding Plaintiffs' Claims in Deference to FDA's Primary Jurisdiction

The Court should further dismiss all remaining claims under the primary jurisdiction doctrine. The resolution of Plaintiffs' claims is inextricably linked with pending FDA regulatory action, and the Court should abstain from intruding upon FDA's expertise.

The primary jurisdiction doctrine "calls for judicial abstention in cases where protection of the integrity of a regulatory scheme dictates primary resort to the agency which administers the scheme." *Global Naps*, *Inc*. *v*. *Bell Atl.-N.J.*, *Inc*., 287 F. Supp. 2d 532, 549 (D.N.J. 2003) (quoting *Cheyney State Coll*. *Faculty v*. *Hufstedler*, 703 F.2d 732, 736 (3d Cir. 1983)). Its application turns on four factors: (1) whether the question "is within the conventional experience of judges" or "involves technical or policy considerations within the agency's particular field of

expertise"; (2) whether the question "is particularly within the agency's discretion"; (3) whether there exists "a substantial danger of inconsistent rulings"; and (4) whether a "prior application to the agency has been made." *Raritan Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 691 (3d Cir. 2011) (quoting *Global Naps*, 287 F. Supp. 2d at 549). All four factors favor abstention here.

First, Plaintiffs' allegations require investigation into technical issues delegated to FDA's expertise, including whether Defendants' MCDs are bioequivalent in their pharmacokinetic profiles to the RLDs, should be "A/B rated" and listed in FDA's "Orange Book," are manufactured in accordance with cGMPs, meet FDA's safety, quality, purity, identity, and strength standards, and conform to FDA-approved labeling.[14] Those are matters outside the Court's conventional expertise and squarely within FDA's expertise. *See* 21 U.S.C. §§ 321, 371-72, 375, 393(a). FDA "has primary jurisdiction to make the initial determination on issues within its statutory mandate[.]" 21 C.F.R. § 10.25(b). Plaintiffs acknowledge FDA's "worldwide jurisdiction to enforce these regulations[.]" Am. Compl. ¶ 139.

Second, Plaintiffs concede that FDA has responsibility for many discretionary matters underlying Plaintiffs' allegations, including the generic drug approval

[14] *See* Am. Compl. ¶¶ 6-7, 12-18, 82, 115-119, 123-25, 127, 135, 137-45, 147, 153, 156, 162-255, 271-78, 289-95, 304-06, 309, 317, 320, 331, 334, 333, 338-39, 361-64, 366-68, 373-74, 376-77, 417-18, 426, 430-31, 439, 495-98, 505-08, 515-17, 523-25, 538-39, 551-52, 557, 559.

framework, bioequivalence determinations and "A/B ratings," maintaining the "Orange Book," the promulgation and enforcement of cGMPs, the "quality control unit," the interim safety limit for NDMA, sampling and testing of materials and drug products, warning letters, inspections, recalls, labeling, and responding to citizen petitions.[15] FDA also has discretion with respect to the commencement, classification, conduct, and termination of recalls. *See* 21 C.F.R. §§ 7.40–7.59. Plaintiffs' claims rest on allegations pertaining to recalls of MCDs and assertions that these recalls are just the "tip of the iceberg." Am. Compl. ¶¶ 1, 177, 234, 262, 271-78, 292-94, 337, 339, 343, 540.

Third, Plaintiffs' claims give rise to a substantial danger of inconsistent rulings. Plaintiffs seek to adjudicate whether any of Defendants' generic MCDs contain NDMA and whether Defendants have complied with federal regulatory requirements, and pray for declaratory, injunctive and monetary relief, including injunctive relief ordering recalls and ensuring Defendants comply "with all proper quality and safety standards going forward." (*Id*. ¶¶ 357, 543, Prayer for Relief.) At the same time, Plaintiffs allege FDA remains actively engaged in ongoing regulatory action with future action possible. (*Id*. ¶¶ 267-61, 281-87, 344.) Indeed, Plaintiffs' claims against Defendants who manufactured and sold only IR products are directly

[15] *See* Am. Compl. ¶¶ 6, 8, 113-25, 136, 138-39, 152, 156, 167-68, 174, 176, 179, 181, 188-91, 192, 198, 203, 209, 211-13, 218, 224, 226, 260, 262, 272-78, 280-85, 292, 322.

contradicted by FDA's own testing detecting no NDMA in such products and FDA's decision not to recall any IR products, and FDA likewise has called into question the testing methodology utilized by Valisure, the company that performed testing upon which Plaintiffs rely. *See, e.g.*, FDA, Questions and Answers: NDMA Impurities in Metformin Products (available at https://www.fda.gov/drugs/drug-safety-and-availability/questions-and-answers-ndma-impurities-metformin-products); FDA, Update – The APPS Journal Publishes FDA Paper on Metformin Testing (July 2, 2020) (available at https://www.fda.gov/drugs/drug-safety-and-availability/fda-updates-and-press-announcements-ndma-metformin).

FDA's actions confirm that it has exercised and continues to exercise its primary jurisdiction over the same subject matter and further highlights the danger of inconsistency. FDA issued its first guidance to industry regarding nitrosamines in drug products in September 2020, and revised it in February 2021. *See* FDA, *Control of Nitrosamine Impurities in Human Drugs: Guidance for Industry* (September 2020) (the "Guidance") (available at https://www.fda.gov/media/141720/download). The Guidance makes clear that FDA "continues to investigate possible NDMA impurities in metformin." *Id*. at 2-3.

Fourth, FDA has an ongoing, multidisciplinary investigation underway to evaluate and address potential impurities in metformin. *See* Guidance at 2-3. Where an issue is "presently pending" before FDA, that weighs in favor of abstention. *See*

Gisvold v. Merck & Co., 62 F. Supp. 3d 1198, 1204 (S.D. Cal. 2014). The test is only whether the agency "has previously considered" the question at issue. *Raritan Baykeeper v. NL Indus., Inc.*, 660 F.3d 686, 692 (3d Cir. 2011). Here, because the issues before this Court are "factually and legally intertwined" with those "pending resolution" before FDA, abstention on primary jurisdiction grounds is fully appropriate. *Iowa Network Servs. v. AT&T Corp.*, No. 3:14-cv-3439, 2019 WL 4861438, at *6 (D.N.J. Oct. 2, 2019) (citation omitted)).

D. The New Jersey and TPP Plaintiffs' Claims Are Subsumed by the New Jersey Products Liability Act

The claims of the New Jersey Plaintiffs (Brzozowski and Harris) and TPP Plaintiff (MSPRC) for breach of implied warranty (Counts III and IV), unjust enrichment (Counts XIII and XIV), negligence (Counts XV and XVI), and negligence per se (Counts XVII and XVIII) are subsumed by the New Jersey Products Liability Act, N.J.S.A. §§ 2A:58C-1 *et seq*. ("PLA").[16] The PLA supplies

[16] This Court applies New Jersey conflict of laws rules in determining the law applicable to Plaintiffs' claims. *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941); *Thabault v. Chait*, 541 F.3d 512, 535 (3d Cir. 2008). In the event of a substantive conflict, the Court should apply the law of the state with the "most significant relationship" to the dispute. *P.V. v. Camp Jaycee*, 962 A.2d 453 (N.J. 2008) (citing *Restatement (Second) of Conflict of Laws* § 6 1971)); *see also Grandalski v. Quest Diag. Inc.*, 767 F.3d 175, 180 (3d Cir. 2014). With respect to the Consumer Plaintiffs, for purposes of this motion, Defendants assume the state with the most significant relationship to each Plaintiff's claims is the Plaintiff's state of residence—thus, New Jersey for Brzozowski and Harris. *See* Am. Compl. ¶¶ 12, 14, 17. The TPP Plaintiff, MSPRC, purports to be the assignee of healthcare benefit providers from multiple states alleged to have paid for MCDs in nearly every state.

"one unified, statutorily defined theory of recovery for harm caused by a product[.]" *In re Lead Paint Litig.*, 191 N.J. 405, 924 A.2d 484, 503 (2007). Except for breach of express warranty, "all claims for harm caused by a product under New Jersey law, ***regardless of the theory underlying the claim***, are governed by the [PLA]," and the PLA "is the ***exclusive remedy*** for such actions and other claims are subsumed within the statutory cause of action." *Calender v. NVR Inc.*, 548 F. App'x 761, 764 (3d Cir. 2013) (emphases added).

It is "the nature of the claims brought, and not the nature of the damages sought, that is dispositive of whether the PLA precludes the separate causes of action." *Sun Chem. Corp. v. Fike Corp*., 235 A.3d 145, 148 (N.J. 2020).[17] A claim is subsumed where "plaintiffs' allegations" demonstrate that "[t]he heart of [their] case [was] the potential for harm caused by" a defendant's drug. *Id*. at 154 (quoting *Sinclair v. Merck & Co*., 948 A.2d 587, 596 (N.J. 2008)). Thus, the PLA subsumes claims solely for economic loss where the core of such claims sounds in tort. *See*

See id. ¶¶ 19-27. Under these circumstances, with no single state alleged to have the most significant relationship to the dispute, "the presumption is to apply the law of the forum." *Lebegern v. Forman*, 471 F.3d 424, 433 (3d Cir. 2006). *See also In re Accutane Litig.*, 194 A.3d 503, 517-24 (N.J. 2018) (applying the PLA where there was "a rather diffuse interest among the states"). Thus, the PLA is presumed to apply to MSPRC's claims.

[17] In *Sun Chemical*, the Supreme Court of New Jersey clarified that, "[i]f a claim is premised upon a product's manufacturing, warning, or design defect," it "must be brought under the PLA with damages limited to those available under that statute," whereas "if a claim is based on deceptive, fraudulent, misleading, and other unconscionable commercial practices, it is not covered by the PLA[.]" *Id*. at 336-37.

McDarby v. Merck & Co., 401 N.J. Super. 10, 97 (App. Div. 2008) (holding claim for economic loss from misrepresentations of a prescription drug's safety was subsumed by PLA because "what [the plaintiffs] are asserting is, at its core, that [defendant] failed to warn of dangers from a product of which it had knowledge, resulting in alleged economic harm to them").

Plaintiffs' claims are for "harm caused by a product[.]" *See* N.J.S.A. § 2A:58C-1(b)(3). The Amended Complaint's claims for breach of implied warranty, unjust enrichment, negligence, and negligence per se facially allege and rest on allegations of defective manufacturing and the purported resulting sale of "adulterated" and "misbranded" MCDs and alleged introduction of a "carcinogen" for "human consumption." *See* Am. Compl. ¶¶ 137-61, 175-271, 384-86, 395-97, 483, 489, 494-99, 504-09, 514-17, 522-25.

These claims contain all the hallmarks of a "product liability action" under the PLA; they are claims for harm allegedly caused by the manufacture and sale of purportedly defective products. Plaintiffs' claims are therefore subsumed. *See, e.g., Kuhar v. Petzl Co.*, No. 16-395, 2016 WL 3921145, at *3-4 (D.N.J. July 19, 2016) (negligence and breach of implied warranty claims subsumed); *Cole v. NIBCO, Inc.*, No. 3:13-cv-07871, 2015 WL 2414740, at *5-14 (D.N.J. May 20, 2015) (tort, breach

of warranty, and unjust enrichment claims subsumed).[18]

A defendant is liable under the PLA only if the defect causes personal injury, not economic losses. *See DeBenedetto v. Denny's*, 421 N.J. Super. 312, 323 (Law Div. 2010), *aff'd*, 2011 N.J. Super. Unpub. 2011 WL 67258 (App. Div. Jan. 11, 2011), *cert. denied*, 205 N.J. 519 (2011) (dismissing consumer fraud claim seeking only economic losses). Economic losses, however, are all that Plaintiffs seek here (*i.e.*, the purchase price of the MCDs). Because Plaintiffs' tort-based claims for negligence, breach of warranty, and unjust enrichment are subsumed by the PLA and seek only economic loss for the value of the drug purchased, they are barred under the PLA and should be dismissed. *See Sinclair*, 948 A.2d at 594 (dismissing medical monitoring claims because the PLA "require[s] a physical injury").

E. Plaintiffs' Breach of Implied Warranty Claims Fail Due to Subsumption, Inability to Prove an Actual Injury or Loss of Metformin's Therapeutic Benefits, and Lack of Privity

Plaintiffs' claims for breach of the implied warranties of merchantability and fitness (Counts III and IV) are premised on the notion that Plaintiffs may have

[18] *See also Port Auth. of N.Y. N.J. v. Arcadian Corp.*, 189 F.3d 305, 313 (3d Cir. 1999); *Brown ex rel. Estate of Brown v. Philip Morris Inc.*, 228 F. Supp. 2d 506, 515-17 (D.N.J. 2002); *Thomas v. Ford Motor Co.*, 70 F. Supp. 2d 521, 528-29 (D.N.J. 1999); *Reiff v. Convergent Techs.*, 957 F. Supp. 573, 583 (D.N.J. 1997); *McWilliams v. Yamaha Motor Corp. USA*, 780 F. Supp. 251, 262 (D.N.J. 1991), *aff'd in part, rev'd in part on other grounds*, 987 F.2d 200 (3d Cir. 1993); *Green v. Gen. Motors Corp.*, 310 N.J. Super. 507, 709 A.2d 205, 209 (N.J. App. 1998); *Ramos v. Silent Hoist Crane Co.*, 256 N.J. Super. 467, 607 A.2d 667, 670 (N.J. App. 1992).

unwittingly purchased MCDs containing unsafe levels of nitrosamines. Plaintiffs' implied warranty claims fail under all applicable state laws for lack of privity and failure to demonstrate an actual injury or loss of the MCDs' therapeutic benefits.

1. Plaintiffs' Breach of Implied Warranty Claims Fail Under Indiana and New Jersey Law

As a threshold matter, the New Jersey and TPP Plaintiffs' claims for beach of implied warranty are subsumed by the PLA. *See* § II.D, *supra*; *see also Kury v. Abbott Labs*., *Inc.*, No. CIV.A. 11-803 FLW, 2012 WL 124026, at *3 (D.N.J. Jan. 17, 2012); *Smith v. Merial Ltd.*, No. 10-439, 2011 WL 2119100, at *3-4 (D.N.J. May 26, 2011); *O'Donnell v. Kraft Foods, Inc.*, No. 09-4448 2010 WL 1050139, at *3 (D.N.J. Mar. 18, 2010); *Levinson v. Johnson & Johnson Consumer Cos.*, No. 09-CV-3317 (DMC), 2019 WL 421091 (D.N.J. Feb. 1, 2010).

Plaintiffs' claims also fail under New Jersey and Indiana law because they do not allege Plaintiffs suffered any present physical harm or were deprived of their MCDs' therapeutic benefits. To state an implied warranty claim under New Jersey law, Plaintiffs must show how an alleged defect impaired the product's functionality or caused actual injury, not merely that a defect or impurity existed. *See Hoffman v. Nutraceutical Corp.,* No. 12-5803, 2013 WL 2650611, at *4 (D.N.J. June 10, 2013) (dismissing implied warranty claim for lead-containing supplement because plaintiff failed to plead or demonstrate injury); *see also Hammer v. Vital Pharms., Inc.,* No. 11-4124, 2012 WL 1018842, at *12 (D.N.J. Mar. 26, 2012); *Bowman v. Ram Med.,*

Inc. No. 10-cv-4403, 2012 WL 1964452, at *5 (D.N.J. May 31, 2012); *Crozier v. Johnson & Johnson Consumer Cos., Inc.,* 901 F. Supp. 2d 494, 508–509 (D.N.J. 2012). Similarly, Indiana law requires Plaintiffs to show that the product is not "fit for the ordinary purposes for which such goods are used." *Irmscher Suppliers, Inc. v. Schuler*, 909 N.E.2d 1040, 1048 (Ind. Ct. App. 2009).

Here, Plaintiffs do not allege they experienced any actual injury, impairment of functionality, or unfitness from their individual MCD purchases, or even that their individual purchases contained nitrosamines. Having failed to allege their MCDs either failed to provide the anticipated therapeutic benefit or caused some adverse health effect, Plaintiffs' breach of implied warranty claims cannot proceed.

2. Plaintiffs' Breach of Implied Warranty Claims Fail Under California and New York Law

Plaintiffs also fail to state an implied warranty claim under California and New York law. To state a claim for breach of the implied warranty of merchantability in California, a plaintiff must allege a fundamental defect that renders the product unfit for its ordinary purpose. *See* Cal. Civ. Code § 1790(a); *see also Tietsworth v. Sears*, 720 F. Supp. 2d 1123, 1142 (N.D. Cal. 2010); *Mexia v. Rinker Boat Co.*, 174 Cal. App. 4th 1297, 1303 (2009). Plaintiffs "must show that the product 'did not possess even the most basic degree of fitness' for its ordinary use, or its intended use." *Mocek v. Alfa Leisure, Inc.,* 114 Cal. App. 4th 402, 406 (2003). Additionally, California's Song-Beverly Consumer Warranty Act requires

vertical privity. *See Tietsworth*, 720 F. Supp. 2d at 1143.

Similarly, in New York, where no personal injury is alleged there is no cognizable claim for breach of the implied warranty of merchantability from a manufacturer to a remote purchaser not in privity with the manufacturer. *See Cummings v. FCA US LLC,* 401 F. Supp. 3d 288, 309 (N.D.N.Y. 2019) ("New York courts … have routinely required a showing of privity for claims under a theory of breach of implied warranty where only economic injury was claimed…."); *see also Adirondack Combustion Tech., Inc. v. Unicontrol, Inc.*, 793 N.Y.S.2d 576, 579 (N.Y. App. Div. 3rd Dept. 2005).

Plaintiffs have alleged no facts plausibly demonstrating that their individual MCD purchases even contained nitrosamines, much less that they lacked therapeutic efficacy, caused Plaintiffs' harm, or otherwise did not possess the requisite degree of fitness for ordinary use. Moreover, Plaintiffs' allegations do not establish vertical privity between Plaintiffs and Defendants. Plaintiffs do not allege they purchased their MCDs directly from any manufacturers, they had any relationship with any manufacturers, or Plaintiffs and the manufacturers even had mutual awareness of one another in connection with any transaction at issue. Accordingly, the California and New York Plaintiffs' breach of implied warranty claims should be dismissed.

F. Plaintiffs' Breach of Express Warranty Claims Fail Because They Do Not Plead Any Specific Warranty Language Forming the Basis of Any Bargain

Plaintiffs' claims for breach of express warranties (Counts I and II) fail under each applicable state's laws because the pleadings fail to allege how any specific warranty language formed the basis of any bargain between Plaintiffs and Defendants.

To state a claim for breach of express warranty under New Jersey law, a plaintiff must allege: "(1) defendant made an affirmation, promise or description about the product; (2) that this affirmation, promise or description became part of the basis of the bargain for the product; and (3) that the product ultimately did not conform to the affirmation, promise or description." *Arlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 706 (D.N.J. 2011); *see also* N.J. Stat. § 12A:2-313(a)-(c); *Snyder v. Farnam Co., Inc.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011).

Under California law, "[b]reach of express warranty requires the exact terms of the warranty, plaintiff's reasonable reliance and a breach which proximately caused plaintiff injury." *Williams v. Beechnut Nutrition Corp.*, 185 Cal. App. 3d 135, 142 (1986). California also requires the purported express warranty to become part of the "basis of the bargain." *See* Cal. Com. Code § 2313(1)(a)-(c). New York and Indiana also have adopted "basis of the bargain" requirements. *See* NY CLS UCC §2-313(1); I.C. § 26-1-2-313; *see also Belden Inc. v. Am. Elec. Components, Inc.*,

885 N.E.2d 751, 762 (Ind. Ct. App. 2008).

Plaintiffs have not alleged any specific express warranty language formed the basis for any bargain between any Plaintiff and any Defendant. Although Plaintiffs generally identify various materials they label as express warranties (in the form of internet advertising and marketing materials, *see* Am. Compl. ¶¶ 279-336), they do not allege what—if anything—any Plaintiff ever saw or read *before* filling an MCD prescription that constituted a warranty upon which he or she relied. At a minimum, to allege that a putative express warranty became part of the basis of the parties' bargain, Plaintiffs must allege they "bought a product *based on* a particular promise[.]" *Mladenov v. Wegmans Food Markets, Inc.,* 124 F. Supp. 3d 360, 378 (D.N.J. 2015) (emphasis added). That requires Plaintiffs to demonstrate they first "saw" the warranty and "purchased [the products] as a result." *Id.; see also Walters v. Carson,* No. 11-6545, 2012 WL 6595732, at *3 (D.N.J. Dec. 17, 2012). The Amended Complaint does not contain any such allegations. It certainly does not identify the specific language on which any Plaintiff relied or its source, as is also required to state an express warranty claim. *See Arlandson*, 792 F. Supp. 2d at 707; *In re Avandia Mktg., Sales Prac. and Prods. Liab. Litig.*, 588 Fed. App'x 171, 175 (3d Cir. 2014) (applying New Jersey law); *Fishman v. Gen. Elec. Co.*, No. 2:12-cv-00585, 2013 WL 1845615, at * 5 (D.N.J. Apr. 30, 2013). Therefore, the express warranty claims are legally insufficient and should be dismissed.

G. Plaintiffs' Magnuson-Moss Warranty Act Claims Fail

Counts V and VI of the Amended Complaint assert claims under the Magnuson-Moss Warranty Act ("MMWA"). Plaintiffs' MMWA claims fail for three reasons. First, the MMWA is inapplicable to MCDs because federal law controls the content of a generic drug's label. *See* 15 U.S.C. § 2311(d) (stating MMWA does not apply to "any written warranty the making or content of which is otherwise governed by Federal law"); *In re Valsartan, Losartan, & Irbesartan Prod. Liab. Litig.*, MDL No. 2875 (RBK-JS), 2021 WL 222776, at *21 (D.N.J. Jan. 22, 2021) (holding the MMWA "prohibits warranty claims involving FDA-regulated items") (citing *Hernandez v. Johnson & Johnson Consumer, Inc.*, No. 3:19-cv-15679-BRM-TJB, 2020 WL 2537633, at *5 (D.N.J. May 19, 2020)); *Dopico v. IMS Trading Corp.,* No. 14-cv-1874, 2018 WL 4489677, at *6 (D.N.J. Sept. 18, 2018) (same). Second, Plaintiffs "cannot meet the pleading requirements of the MMWA because Plaintiffs failed to present to any defendant that the drug was contaminated and sought a 'repair.'" *In re Valsartan*, 2021 WL 222776, at *21; *see also* 15 U.S.C. § 2310(e) (requiring "a reasonable opportunity to cure such failure to comply"). Third, Plaintiffs' MMWA claims fail for the same reasons as Plaintiffs' implied and express warranty claims. *See, e.g., Johansson v. Cent. Garden & Pet Co.,* 804 F. Supp. 2d 257, 265 (D.N.J. 2011) (dismissing MMWA claim where underlying state claim was dismissed). Therefore, Plaintiffs' MMWA claims should be dismissed.

H. Plaintiffs' Fraud and State Consumer Protection Claims Fail for Lack of Particularity, Untimeliness, and Failure to State a Claim

Plaintiffs' claims for common law fraud (Counts VII and VIII), negligent misrepresentation (Counts IX and X) and violation of state consumer protection statutes (Counts XI through XII and XIX through XXII) are all based on Defendants' purported misrepresentations and omissions as to the properties of their MCDs. Those claims remain facially defective because they fail to allege fraud with sufficient particularity, allege claims that are time-barred in whole or in part, and fail to allege the requisite elements of each claim.

1. Plaintiffs' Claims Do Not Satisfy the Heightened Pleading Standard for Actions Sounding in Fraud

Plaintiffs' common law fraud (Counts VII and VIII), negligent misrepresentation (Counts IX and X), and Indiana, New Jersey, and California consumer protection claims (Counts XI to XII and XIX to XX) all sound in fraud and fail to satisfy the applicable "heightened specificity requirements" of Rule 9(b). *MDNet, Inc. v. Parmacia Corp.*, 147 F. App'x 239, 245 (3d Cir. 2005); *see also Travelers Indem. Co. v. Cephalon, Inc.*, 620 F. App'x 82, 85 n.3 (3d Cir. 2015) (negligent misrepresentation); *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009) (California consumer protection); *Smajlaj v. Campbell Soup Co.*, 782 F. Supp. 2d 84, 97 (D.N.J. 2011) (New Jersey consumer protection); *SMC Corp. v. Peoplesoft USA, Inc.*, No. 1:00-CV-01095-LJM-VS, 2004 WL 2538641, at *5 (S.D.

Ind. Oct. 12, 2004) (Indiana consumer protection). Each count relies upon allegations of fraud, *see* Am. Compl. ¶¶ 415-25, 428-38, 441-51, 454-64, 467-69, 473-75, 528-38, 544-60, yet fails to plead fraud with particularity.

To satisfy Rule 9(b), Plaintiffs must allege facts detailing the "who, what, when, where, and how" of their fraud claims. *Rapid Models & Prototypes, Inc. v. Innovated Sols.*, 71 F. Supp. 3d 492, 504 (D.N.J. 2014). A fraud claim also will be dismissed where a "Plaintiff lumps all [defendants] together as having engaged in wrongful conduct without specifying which defendant was responsible for which actions." *Snyder v. Dietz & Watson, Inc.*, 837 F. Supp. 2d 428, 450 (D.N.J. 2011).

Here, Plaintiffs' allegations are devoid of specific facts alleging how any Plaintiff was deceived by any Defendant with respect to the alleged NDMA impurities in MCDs. Plaintiffs do not allege who made purported misrepresentations to each Plaintiff, what was said, when or where the statements were made, or how each Plaintiff was deceived. The Amended Complaint does not allege any misstatements or omissions on the part of any individual or any Defendant with particularity. And Plaintiffs routinely lump claims against most or all Defendants together without pleading particular facts regarding the alleged misconduct of each Defendant. That lack of particularity requires Plaintiffs' claims to be dismissed.

2. Plaintiffs' Claims Are Partially or Wholly Time-Barred

Plaintiffs' fraud-based claims are also partially or wholly barred by the applicable statutes of limitations. As with the original Complaint, the Amended Complaint fails to allege when any named Plaintiffs purchased their MCDs, instead alleging identically as to each Plaintiff, "During the class period, Plaintiff paid money for one or more of the Defendants' MCDs." Am. Compl. ¶¶ 12-18. The "class period," however, contains no time limitations. *Id.* at ¶¶ 329-31. Based on Plaintiffs' earlier-filed individual complaints, Plaintiffs' individual purchases date back as early as 1993. *See, e.g.*, Case 2:20-cv-02324, Dkt. 1 (Joseph Brzozowski) ¶ 92 (listing MCD purchases from 2009 to 2017); Case No. 2:20-cv-03757, Dkt. 1 (Mohammed Rahman) ¶ 17 (alleging MCD purchases "since 1993"); Case 2:20-cv-04329 (Stelios Mantalis) ¶ 17 (alleging MCD purchases "since 2011").

The applicable statutes of limitations for Plaintiffs' fraud claims range from three to six years. *See* Cal. Code Civ. Proc. § 338(d) (three years); Ind. Code § 34-11-2-7 (six years); N.J.S.A. § 2A:14-1 (six years); N.Y. CPLR § 213[8] (three years). For Plaintiffs' negligent misrepresentation claims, the range is two to six years. *See* Cal. Code Civ. Proc. § 339(1) (two years); Ind. Code § 34-11-2-4 (two years); N.J.S.A. § 2A:14-1 (six years); N.Y. CPLR § 213 (six years). For Plaintiffs' statutory consumer protection claims, the range is two to six years. Cal. Code Civ. P. § 1783

(three years); Cal. Bus. & Prof. Code § 17208 (four years); Ind. Code § 24-5-0.5-5(b) (two years); N.J.S.A. § 2A:14-1 (six years); N.Y. CPLR § 214[2] (three years).

Plaintiffs' fraud-based claims are therefore time-barred to the extent Plaintiffs assert such claims for purchases made outside the limitations period, and the Court should dismiss all such time-barred claims.

3. Plaintiffs Fail to State a Claim for Common Law Fraud Because They Do Not Allege Defendants' Knowledge or Scienter

Plaintiffs' common law fraud counts (Counts VII and VIII) additionally fail because Plaintiffs cannot satisfy the element of knowledge or scienter. Plaintiffs assert that all Defendants "knew ***or should have known***" of their putative misrepresentations and omissions. *See* Am. Compl. ¶¶ 383, 394, 417-19 (emphasis added). That is insufficient. Though expressed somewhat differently among states, all of Plaintiffs' states require an element of knowledge or scienter demanding ***actual*** knowledge or, at a minimum, reckless ignorance. *See*, *e.g.*, *Conroy v. Regents of University of California*, 45 Cal. 4th 1244, 1255 (Cal. 2009) (knowledge of falsity); *Rice v. Strunk*, 670 N.E.2d 1280, 1289 (Ind. 1996) (knowledge or reckless ignorance); *Gennari v. Weichert Co. Realtors*, 691 A.2d 350, 367 (N.J. 1997) (knowledge or belief of falsity); *People v. Credit Suisse Sec. (USA) LLC*, 31 N.Y.3d 622, 638 (N.Y. 2018) (knowledge of falsity). Plaintiffs' allegations do not satisfy any variation of that element.

Plaintiffs do not allege any facts plausibly demonstrating that any Defendant actually knew or was recklessly ignorant to alleged nitrosamine "contamination" in its MCDs. The closest Plaintiffs come to such an allegation is an assertion of "indications that Defendants had actual knowledge," without stating what those "indications" were, as well as conclusory use of the adverb "knowingly" without any accompanying allegations of fact demonstrating such knowledge.[19] *See* Am. Compl. ¶¶ 270-71. Those conclusory assertions are insufficient. *See, e.g.*, *Cansino v. Bank of Am.*, 224 Cal. App. 4th 1462, 1472 (Cal. Ct. App. 2014) (finding conclusory assertion of knowledge failed to satisfy knowledge element of fraud); *Wilson v. Palmer*, 452 N.E.2d 426, 428 (Ind. Ct. App. 1983) (same); *Hoffman v. Hampshire Labs, Inc.*, 405 N.J. Super. 105, 116, 963 A.2d 849, 855 (Super. Ct. App. Div. 2009) (same); *Eurycleia v. Seward Kissel*, 12 N.Y.3d 553, 559, 883 N.Y.S.2d 147, 910 N.E.2d 976 (N.Y. 2009) (same). Having failed to allege facts supporting the necessary knowledge or scienter element, Counts VII and VIII should be dismissed.

[19] Indeed, Plaintiffs' allegations affirmatively concede Defendants' ***lack*** of actual knowledge, asserting that had Defendants adhered to FDA's guidelines, they "would have" identified or discovered the presence of nitrosamine. Am. Compl. ¶¶ 265, 269. The use of the past modal tense ("would have identified") signifies that Defendants ***did not in fact*** know of the alleged presence of nitrosamines.

4. Plaintiffs Fail to State a Claim for Negligent Misrepresentation

Though the existence and elements of negligent misrepresentation vary widely by state, Plaintiffs' negligent misrepresentation counts fail to state a claim under any applicable state law. Indiana applies negligent misrepresentation "narrowly" only to the employer-employee relationship and "those whose profession includes the giving of opinions" like "brokers, attorneys, abstractors, and surveyors." *Troth v. Warfield*, 495 F. Supp. 3d 729, 742-43 (N.D. Ind. 2020); *see also Barna Log Sys. Mid. v. Gen. Cas. Ins. Co.*, 791 N.E.2d 816, 830 (Ind. Ct. App. 2003). No such relationship is alleged here.

California law requires Plaintiffs to allege Defendants lacked any "reasonable ground for believing" the truth of their statements. *Conroy*, 45 Cal. 4th at 1255. Plaintiffs allege no facts indicating Defendants had any reason to believe their MCDs contained NDMA above safety limits prior to the submission of the Valisure Citizen Petition on March 2, 2020. *See* Am. Compl. ¶¶ 265-67.

New Jersey law requires Plaintiffs to allege they suffered "quantifiable damages proximately caused by the negligent misrepresentation." *Singer v. Beach Trading Co.*, 379 N.J. Super. 63, 69, 876 A.2d 885, 888 (N.J. Super. Ct. App. Div. 2005). As discussed earlier with respect to standing, Plaintiffs lack any basis to quantify the value of their supposed economic loss for purchasing and ingesting MCDs that worked as intended and did not injure them.

New York law requires Plaintiffs to allege "the existence of a special or privity-like relationship imposing a duty on the defendant to impart correct information to the plaintiff[.]" *Mandarin v. Wildenstein*, 16 N.Y.3d 173, 180, 919 N.Y.S.2d 465, 944 N.E.2d 1104 (N.Y. 2011) (citation omitted). "A 'privity-like' relationship does not exist when a plaintiff is one of a large class of possible consumers." *Mahoney v. Endo Health Sols., Inc.*, No. 15cv9841(DLC), 2016 WL 3951185, at *3 (S.D.N.Y. July 20, 2016) (citing *Sykes v. RFD Third Ave. 1 Associates, LLC*, 67 A.D.3d 162, 884 N.Y.S.2d 745, 749 (N.Y. App. Div. 1st Dep't 2009)). The relationship between "an ordinary consumer and a prescription drug manufacturer" also does not satisfy the relationship requirement. *Id*. at *11. *See also Becker v. Cephalon, Inc.*, No. 14 Civ. 3864 (NSR), 2015 WL 5472311, at *9 (S.D.N.Y. Sep. 15, 2015) (same). All Plaintiffs' negligent misrepresentation claims therefore should be dismissed.

5. Plaintiffs Fail to State a Claim Under State Consumer Protection Laws

(a) Plaintiffs Do Not State a Claim for Violation of California's Consumer Protection Statutes

Counts XI, XII, XIX and XX fail to allege facts supporting violations of California's Unfair Competition Law ("UCL"), False Advertising Law ("FAL"), or Consumers Legal Remedies Act ("CLRA"). Am. Compl. ¶¶ 467, 473, 525-60.

The UCL and FAL require Plaintiffs to allege an "injury in fact" and loss of

"money or property as a result of" the alleged violation as statutory standing preconditions to sue under either law. *Kwikset Corp. v. Superior Court*, 51 Cal. 4th 310, 321-22 (Cal. 2011) (quoting Cal. Bus. & Prof. Code §§ 17204, 17535). The CLRA likewise requires Plaintiffs to allege actual damages caused by Defendants' supposed unlawful practices. *See* Cal. Civ. Code §§ 1780(a), 1781(a); *see also Steroid Hormone Product Cases*, 181 Cal. App. 4th 145, 156 (Cal. Ct. App. 2010). As previously addressed, *see* § II.A.1, *supra*, Plaintiffs have not alleged an injury in fact or damages from purchasing and using their MCDs.

Further, Plaintiffs' California claims expressly rely on allegations sounding in fraud. *See* Am. Compl. ¶¶ 467, 460, 473, 476, 532-34, 551-52. Plaintiffs therefore must not only satisfy Rule 9(b)'s particularity requirements, *see* § II.H.1, *supra*, but also must plead actual knowledge of falsity, just as they must for common law fraud. *See Snyder v. Tamko Bldg. Prods.*, No. 1:15-CV-01892-TLN-KJN, 2019 WL 4747950, at *10-11 (E.D. Cal. Sep. 30, 2019). This requires Plaintiffs to allege "***how*** the defendant obtained knowledge of the specific defect ***prior*** to the plaintiff's purchase of the defective product." *Stewart v. Electrolux Home Prods.*, 304 F. Supp. 3d 894, 908 (E.D. Cal. 2018) (citing *Wilson v. Hewlett-Packard Co.*, 668 F.3d 1136, 1145-48 (9th Cir. 2012)) (emphases in original). As discussed above, *see* § II.H.3, *supra*, Plaintiffs fail to allege actual knowledge.

(b) Plaintiffs Do Not State a Claim for Violation of Indiana's Deceptive Consumer Sales Act

Counts XI and XII fail to allege facts supporting a violation of Indiana's Deceptive Consumer Sales Act. Compl. ¶¶ 452, 458. To bring an action for damages under the Indiana statute, Plaintiffs must allege Defendants' purported acts were "uncured or incurable[.]" Ind. Code Ann. §§ 24-5-0.5-2(a)(7)-(8), 24-5-0.5-4(a). An "uncured" deceptive act requires notice and an opportunity to cure, while an "incurable" deceptive act requires "intent to defraud or mislead." Ind. Code Ann. §§ 24-5-0.5-2(a)(7)-(8); *see also Perry v. Gulf Stream Coach, Inc.*, 814 N.E.2d 634, 647 (Ind. Ct. App. 2004). Plaintiffs do not allege they gave notice to any Defendant or afforded any Defendant an opportunity to cure, nor do they allege any Defendant intended to defraud or mislead them.

(c) Plaintiffs Do Not State a Claim for Violation of New Jersey's Consumer Fraud Act

Counts XI and XII also fail to allege facts supporting a violation of New Jersey's Consumer Fraud Act ("CFA"). Am. Compl. ¶¶ 452, 458. The CFA only affords a private remedy to a person who suffers an "ascertainable loss of moneys or property" as a result of the alleged violation. N.J.S.A. § 56:8-19. That requires Plaintiffs to show a "quantifiable loss[.]" *Thiedemann v. Mercedes-Benz USA, LLC*, 183 N.J. 234, 252, 872 A.2d 783, 795 (2005). Plaintiffs cannot satisfy this requirement. *See* § II.A.1, *supra*; *see also Arcand v. Brother Int'l Corp.*, 673 F. Supp.

2d 282, 301 (D.N.J. 2009) (rejecting "hypothetical or illusory" and "wholly subjective" losses).

(d) Plaintiffs Do Not State a Claim for Violation of New York's Consumer Protection Statute

Counts XXI and XXII fail to allege sufficient facts to support violations of New York General Business Law §§ 349-50. Am. Compl. ¶¶ 467, 473, 561-85. Sections 349 and 350 provide that "deceptive acts or practices" and "false advertising" in "the conduct of any business, trade or commerce" are unlawful. N.Y. GEN. BUS. LAW §§ 349(a), 350. A Section 349 claim will not survive where a plaintiff fails to identify any material deceptive acts. *See Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 287 (E.D.N.Y. 2009). And "to state a plausible Section 350 claim, a plaintiff must allege the act, practice or advertisement was consumer-oriented and misleading in a material respect, and that plaintiff was injured as a result." *Medisim Ltd. v. BestMed LLC*, 910 F. Supp. 2d 591, 607 (S.D.N.Y. 2012).

To properly allege causation, Plaintiffs must state that they saw the allegedly misleading statements ***before*** they purchased the MCDs. *See Gale v. Int'l Bus. Machs. Corp.*, 781 N.Y.S.2d 45, 47 (App. Div. 2004). If Plaintiffs did not see the allegedly misleading statements before they bought the MCDs, they could not have been injured by such statements. *Douyon v. N.Y. Med. Health Care, P.C.*, 894 F. Supp. 2d 245, 263 (E.D.N.Y. 2012). Plaintiffs here have failed to identify any material, deceptive acts by any Defendant which they saw before buying their

MCDs. That failure alone defeats Plaintiffs' claims.

Plaintiffs' NYCPL claims also fail because they do not allege an injury. Plaintiffs claim that the MCDs did not have the qualities, uses, or benefits promised, Am. Compl. ¶¶ 572, 584, and they would not have bought the MCDs had they known of the alleged NDMA contamination. But New York courts reject the idea that "consumers who buy a product that they would not have purchased, absent a manufacturer's deceptive commercial practices, have suffered an injury." *Small v. Lorillard Tobacco Co.*, 720 N.E.2d 892, 898 (N.Y. 1999). Moreover, there are no allegations that the MCDs failed to control Plaintiffs' blood sugar or caused ill effects or even that they contained elevated levels of nitrosamines. As such, Plaintiffs have not alleged any cognizable injury, and their NYCPL claims should be dismissed. *See Horowitz*, 613 F. Supp. 2d at 287 (dismissing NYCPL claims where plaintiff "provides no connection between the defendants' deceptive conduct and a specific injury that she suffered as a result").

I. Plaintiffs' Negligence and Negligence Per Se Claims Fail

Plaintiffs negligence claims (Counts XV-XVIII) premised on the sale of allegedly "contaminated" MCDs fail for two reasons.

First, as explained above, the New Jersey PLA subsumes common law negligence claims asserting causes of action rooted in product liability and bars claims seeking solely economic loss for the value of the purportedly defective

product, which is exactly what Plaintiffs seek here. *See supra*, §§ II.D, II.E.

Second, common law negligence claims require sufficient allegations of proximate cause and injury. Specifically, Plaintiffs must plead the elements of a cause of action for negligence: duty; breach of duty; legal cause; and damages. *Paz v. State of California*, 994 P.2d 975 (Cal. App. 2000); *Solomon v. City of New York*, 489 N.E.2d 1294, 1295 (N.Y. 1985); *Yost v. Wabash College*, 3 N.E.3d 509, 515 (Ind. 2014). Plaintiffs' Amended Complaint still fails to allege facts sufficient to establish causation or injury, thus defeating their negligence claims.

Rather than relying solely on the allegation that they purchased from "one or more" Defendants, Plaintiffs in their Amended Complaint have attempted to name certain defendants from whom they allegedly purchased MCDs. *See* Am. Compl. ¶¶ 13, 15-16, 18. Plaintiffs' allegations still fail, however, because they have not alleged that they consumed MCDs with elevated levels of nitrosamines. Plaintiffs have not identified a single batch or lot from which they allegedly purchased or consumed MCDs, and thus cannot allege such MCDs allegedly contained nitrosamines above regulatory limits that were subject to any FDA recalls. *See id*. Plaintiffs thus fail to connect a purchase to any alleged injury and therefore cannot, as a matter of law, establish proximate cause.

Plaintiffs also fail to allege any injury under any state's law. To have suffered an injury, Plaintiffs must have either not used the MCD and suffered an economic

loss of its value, or taken it and suffered an ill effect. Plaintiffs allege neither. If Plaintiffs took the MCD and it worked as intended (controlled their blood sugar) with no ill effects, there is no injury. Plaintiffs do not allege they took the MCD and it either (a) failed to work as intended, or (b) caused adverse effects.

Plaintiffs' claims thus cannot survive. *See, e.g.*, *Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 99 (S.D.N.Y. 1997) ("It is well established that purchasers of an allegedly defective product have no legally recognizable claim where the alleged defect has not manifested itself in the product they own."); *In re Toyota Motor Corp. Hybrid Brake Mktg. Sales Prac. & Prod. Liab. Litig.*, 915 F. Supp. 2d 1151, 1159 (C.D. Cal. 2013) (dismissing plaintiff's claims that his vehicle was defective due to braking recall because his brakes worked as intended and he thus "received precisely what he bargained for"); *Hughes v. Chattem, Inc.*, 818 F. Supp. 2d 1112, 1120 (S.D. Ind. 2011) (dismissing plaintiffs' claims against supplement manufacturer in which they alleged the possibility of future harm and "wish they had not purchased" supplement after reading adverse online report because such claims do not "come close to establishing injury").

Moreover, under California and New York law, just as in Indiana and New Jersey, economic loss is not recoverable under a negligence theory. *See Rodrigues v. Campell Indus.*, 151 Cal. Rptr. 90, 91 (Cal. App. 1978) (noting that in negligence actions stemming from allegedly defective products, "there is no recovery for

economic loss alone"); *Labajo v. Best Buy Stores, L.P.*, 478 F. Supp. 2d 523, 532 (S.D.N.Y. 2007) (consumer could not bring negligence claim absent "any personal injury or property damage") *Bamberger & Feibleman v. Indianapolis Power & Light Co.*, 665 N.E.2d 933, 937 (Ind. Ct. App. 1996) ("economic losses that do not result from physical harm to person or property are not recoverable in a negligence action"). Thus, although Plaintiffs purport to seek the economic value of the MCDs they purchased, that is not recoverable under a negligence theory. For these reasons, Plaintiffs' negligence claims should be dismissed.

J. Plaintiffs' Unjust Enrichment Claims Fail

Plaintiffs' two unjust enrichment claims (Counts XIII and IV, ¶¶ 477-473) in their Amended Complaint are identical to the same counts in their Complaint and thus once again offer no more than a formulaic recitation of the elements of an unjust enrichment claim. As such, their claim fail to satisfy Rule 8(a). *See Iqbal*, 556 U.S. 662 at 678 (quoting *Twombly*, 550 U.S. at 555) ("[T]he pleading standard Rule 8 announces does not require 'detailed factual allegations,' but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.... A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do."). Plaintiffs do not distinguish between Defendants' putative unjust conduct and do not direct allegations to any individual Defendant, making it impossible to tell which Defendant allegedly was enriched and by whom. Such

generalized pleading is insufficient under Rule 8. *See, e.g.*, *D'Addario v. Johnson & Johnson*, No. 3:10-cv-15627, 2020 WL 3546750, at *6 (D.N.J. June 30, 2020) (quoting *Sheeran v. Blyth Shipholding S.A.*, No. 14-5482, 2015 WL 9048979, at *3 (D.N.J. Dec. 16, 2005) ("'[G]roup pleading' does not satisfy Rule 8[] because it does not place Defendants on notice of the claims against each of them[.]")).

In addition, Plaintiffs' unjust enrichment claims must be dismissed under their respective states' laws because they merely duplicate Plaintiffs' legal claims, amply demonstrating the existence of an adequate remedy at law, and Plaintiffs do not allege otherwise. *See, e.g.*, *Phillips v. Ford Motor Co.*, No. 5:14-cv-2989-LHK, 2015 WL 4111448, at *16 (N.D. Cal. July 7, 2015) (dismissing unjust enrichment claims and noting that "[a] plaintiff seeking equitable relief in California must establish that there is no adequate remedy at law available"); *In re Ford Tailgate Litig.*, No. 3:11-cv-2953, 2014 WL 1007066, at *5 (N.D. Cal. Mar. 12, 2014), *order corrected on denial of reconsideration*, 2014 WL 12649204 (N.D. Cal. Apr. 15, 2014) (dismissing unjust enrichment claim and noting that to the extent "unjust enrichment is available as an independent claim ... it will not stand where the claim simply mirrors other statutory or tort claims"); *Indiana ex rel. Zoeller v. Pastrick*, 696 F. Supp. 2d 970, 999 n.7 (N.D. Ind. 2010) (noting that "[u]nder Indiana law, equitable principles such as unjust enrichment will not apply where there exists a remedy at law") (citation omitted); *Duffy v. Charles Schwab & Co., Inc.*, 123 F. Supp. 2d 802, 814 (D.N.J.

2000) ("Restitution for unjust enrichment is an equitable remedy, available only when there is no adequate remedy at law."); *Clougher v. Home Depot U.S.A., Inc.*, 696 F. Supp. 2d 285, 295 (E.D.N.Y. 2009) (dismissing unjust enrichment claim as duplicative statutory claim where an "adequate legal remedy" exists).

Finally, Plaintiffs have failed to allege they conferred a direct benefit on Defendants or even had a sufficiently direct relationship to do so, as required to support an unjust enrichment claim under New Jersey and New York law. *See, e.g.*, *Arlandson*, 792 F. Supp. 2d at 711 (internal quotation marks and citation omitted) ("Since a plaintiff must confer a benefit on the defendant to support an unjust enrichment claim, this element has been interpreted by New Jersey courts as a requirement that the plaintiff allege a sufficiently direct relationship with the defendant to support the claim."); *Sperry v. Crompton Corp.*, 863 N.E.2d 1012, 1018 (N.Y. 2007) (affirming dismissal of unjust enrichment claim because connection between purchaser of tires and producers of chemicals used in tires "is simply too attenuated to support such a claim"); *Georgia Malone & Co., Inc. v. Rieder*, 973 N.E.2d 743, 747 (N.Y. 2012) (same). Plaintiffs make no allegation that any one of them conferred a direct benefit upon any Manufacturer Defendant. To the contrary, the Amended Complaint indicates that the Manufacturer Defendants did not sell the products directly to consumers and that Plaintiffs are three transactions removed from the manufacturers. *See* Am. Compl. ¶ 84. Accordingly, Plaintiffs do not state

viable claims for unjust enrichment and those claims must be dismissed.

K. The Court Lacks Personal Jurisdiction Over The Non-U.S. Defendants

Lastly, Plaintiffs cannot meet their burden of establishing this Court's personal jurisdiction over the Non-U.S. Defendants. "Once a defendant challenges a court's exercise of personal jurisdiction over it, the plaintiff bears the burden of establishing personal jurisdiction." *D'Jamoos v. Pilatus Aircraft Ltd.*, 566 F.3d 94, 102 (3d Cir. 2009). "[W]hen a suit is brought as a purported class action, personal jurisdiction over ***each defendant*** is assessed with respect to the named plaintiffs' causes of action." *Chernus v. Logitech, Inc.*, No. 17-673(FLW), 2018 WL 1981481, at *3 (D.N.J. Apr. 27, 2018) (collecting cases) (emphases added).

At the outset, Plaintiffs have not properly served the Non-U.S. Defendants. Teva Industries was never served with the operative pleading, just Plaintiff Brzozowski's individual complaint served months ***after*** Plaintiffs' filing of the superseding consolidated Complaint. (Dkt. Nos. 7, 13, 58, 71; *see also* Declaration of Mr. Brian Shanahan ["Shanahan Dec."], Exhibit A ¶ 21). Similarly, Emcure, Alkem, and Aurobindo Pharma Ltd., have not been properly served with the superseding consolidated Complaint or the Amended Complaint. (*See* Declaration of Mr. Gorla Phaneemdra Prasad ["Prasad Dec."], Exhibit B, ¶ 10; Declaration of Amresh Trivedi ["Trivedi Dec."], Exhibit C, ¶ 10; Declaration of Mr. Amit Ghare

["Ghare Dec."], Exhibit D, ¶ 9.)[20] Pursuant to Federal Rule of Civil Procedure 4(c)(1), "[a] summons must be served with a copy of the complaint." Courts have uniformly interpreted this rule to mean that "the summons must be served with a copy of the ***operative complaint*** in the action." *Dorval v. Sapphire Vill. Condo. Ass'n*, No. 2016-50, 2018 WL 2224050, at *5 (D.V.I. May 15, 2018) (emphasis added).[21] Indeed, service of a superseded complaint equates to "no more than a mere 'scrap of paper' insofar as the case is concerned." *PNC Bank, N.A. v. Twin Tier Dev. Grp., Inc.*, No. 3:10-CV-2020, 2010 WL 5300819, at *1 (M.D. Pa. Dec. 20, 2010) (quoting *Phillips*, 194 F. Supp. at 622). Plaintiffs' failure to serve the Non-U.S.

[20] In addition, Emcure, Alkem, and Aurobindo Pharma Ltd. have not been properly served pursuant to the requirements of the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil or Commercial Matters, T.I.A.S. No. 6638, 20 U.S.T. 361, 1969 WL 97765 (the "Hague Convention"). Specifically, although they received certain packages accompanied by a Request for Service Abroad of Judicial or Extrajudicial Documents form required by the Hague Convention, none of the forms included a completed Certificate/Attestation page completed by the applicable Central Authority (which in India is The Ministry of Law and Justice) also required by the Hague Convention. (*See* Prasad Dec., Ex. B, ¶ 9; Trivedi Dec., Ex. C, ¶ 9; Ghare Dec., Ex. D, ¶ 8; *see also*, Hague Conference on International Law Service Section, [available at https://www.hcch.net/en/states/authorities/details3/?aid=712] [listing The Ministry of Law and Justice as India's Central Authority].) Hague Convention, Arts. 5, 6. Despite requests, Plaintiffs have not confirmed if they have received completed certificates from The Ministry of Law and Justice.

[21] *See also Gilles v. United States*, 906 F.2d 1386, 1390 (10th Cir. 1990) ("[W]here an amended pleading supersedes the original complaint, subsequent service of the superseded prior or original pleading is improper."); *Phillips v. Murchison*, 194 F. Supp. 620, 622 (S.D.N.Y. 1961); *TCS Capital Mgmt., LLC v. Apax Partners, L.P.*, No. 06-CV-13447 (CM), 2008 WL 650385, at *10 (S.D.N.Y. Mar. 7, 2008).

Defendants with the operative pleading requires their dismissal. *See Mason v. Therics, Inc.*, No. 08-2404 (RBK), 2009 WL 44743, at *1 (D.N.J. Jan. 6, 2009); *Eastman Kodak Co. v. Studiengesellschaft Kohle mbH*, 392 F. Supp. 1152, 1154 (D. Del. 1975).

Additionally, Plaintiffs have failed to "establish a *prima facie* case of personal jurisdiction" over the Non-U.S. Defendants. *Miller Yacht Sales, Inc. v. Smith*, 384 F.3d 93, 97 (3d Cir. 2004). As Plaintiffs allege, Teva Industries is an Israeli company with its headquarters in Petah Tikvah, Israel; Emcure is a foreign corporation with its principal place of business in Pune, India; Aurobindo Pharma Ltd. is a foreign corporation with its principal place of business in Hyderabad, Telangana, India; and Alkem is a foreign entity headquartered in Mubai, India. Am. Compl. ¶¶ 29, 33, 44, 49; *see also*, Shanahan Dec., Ex. A, ¶ 7 [Teva Industries organized under the laws of Israel]; Prasad Dec., Ex. B, ¶ 2 [Aurobindo Pharma Ltd. organized under the laws of the Republic of India]; Trivedi Dec., Ex. C, ¶ 3 [Emcure organized under the laws of the Republic of India]; Ghare Dec., Ex. D, ¶ 2 [Alkem Laboratories Ltd. organized under the laws of the Republic of India]. As to personal jurisdiction, Plaintiffs merely allege the Court "has personal jurisdiction over Defendants, because Defendants have sufficient minimum contacts in New Jersey, and because Defendants have otherwise intentionally availed themselves of the markets within

New Jersey through their business activities, such that the exercise of jurisdiction by this Court is proper and necessary." *Id*. ¶ 77.

That allegation plainly is insufficient. The Amended Complaint contains no factual allegations concerning any of the Non-U.S. Defendants' contacts with any Plaintiff or with New Jersey, and the Court possesses neither general jurisdiction nor specific jurisdiction over the Non-U.S. Defendants.

General jurisdiction exists over a corporate entity only where "its affiliations with the State are so 'continuous and systematic' as to render [it] essentially at home in the forum state." *Goodyear Dunlop Tires Ops., S.A. v. Brown*, 564 U.S. 915, 919 (2011). For a corporation, "home" is where it is incorporated or organized and where it maintains its principal place of business. *See id.* at 924; *see also Daimler AG v. Bauman*, 571 U.S. 117, 137 (2014). Because all the Non-U.S. Defendants are incorporated outside the U.S. and none have their principal place of business in New Jersey (or anywhere else in the U.S.), they are not "at home" in New Jersey and are not subject to general jurisdiction here.

Specific jurisdiction is equally lacking. For specific jurisdiction to exist, the cause of action must arise out of or relate to the nonresident defendant's contacts with the state. *Bristol-Myers Squibb Co. v. Super. Ct. of California, San Francisco County*, 137 S. Ct. at 1773, 1780 (2017) ("To establish specific jurisdiction, "the *suit must* aris[e] out of or relat[e] to the defendant's contacts with the *forum*." (emphasis

in original)). "Specific jurisdiction ... depends on an 'affiliatio[n] between the forum and the underlying controversy,' principally, activity or an occurrence *that takes place in the forum State*...." *Goodyear*, 564 U.S. at 919 (internal quotations omitted, emphasis added).

Here, Plaintiffs have alleged no facts demonstrating that any of the Non-U.S. Defendants "has 'purposefully directed' [its] activities at residents of" New Jersey and this litigation "results from alleged injuries that 'arise out of or relate to' those activities." *Burger King v. Rudzewicz*, 471 U.S. 462, 476 (1985). Plaintiffs have failed to allege any of the Non-U.S. Defendants "committed at least one act in the relevant forum which is substantially related to the claim[s] being adjudicated." *Grimes v. Vitalink Comms. Corp.*, 17 F.3d 1553, 1559 (3d Cir. 1994). Thus, there is no "affiliation between the forum and the underlying controversy[.]" *Bristol-Myers Squibb Co.*, 137 S. Ct. at 1780.

Plaintiffs not only have not made the requisite jurisdictional allegations establishing personal jurisdiction in this Court; but also they are incapable of doing so. The Non-U.S. Defendants are not incorporated under the laws of the United States or any State, and lack the requisite contacts with Plaintiffs' claims and the forum to establish specific jurisdiction over the Non-U.S. Defendants with respect to Plaintiffs' claims. *See* Shanahan Dec., Ex. A, ¶¶ 8-20; Prasad Dec., Ex. B, ¶¶ 5-8; Trivedi Dec., Ex. C, ¶¶ 3-8; Ghare Dec., Ex. D, ¶¶ 5-6.

Finally, the Court cannot exercise personal jurisdiction over the Non-U.S. Defendants based on alleged jurisdictional contacts of other Defendants. "It is well-established in New Jersey that the forum contacts of a subsidiary corporation will not be imputed to a parent corporation for jurisdictional purposes without a showing of something more than mere ownership." *Seltzer v. I.C. Optics, Ltd.*, 339 F. Supp. 2d 601, 609 (D.N.J. 2004); *see also State, Dep't of Environmental Protection v. Ventron Corp.*, 94 N.J. 473, 468 A.2d 150, 164 (N.J. 1983); *Leo v. Kerr-McGee*, No. 93-1107(JEI), 1996 WL 254054, *5 (D.N.J. May 10, 1996); *Pfundstein v. Omnicom Group*, 285 N.J. Super. 245, 666 A.2d 1013, 1016 (N.J. Super. Ct. App. Div. 1995) (citing cases). Plaintiffs have not made and cannot make such a showing. The Non-U.S. Defendants should be dismissed for lack of personal jurisdiction.

CONCLUSION

WHEREFORE, for the foregoing reasons, the Manufacturing Defendants respectfully request the Amended Complaint be dismissed with prejudice and without leave to amend.

Respectfully submitted,
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